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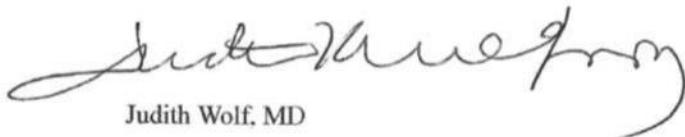
UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES PRACTICES, AND
PRODUCTS LIABILITY LITIGATION

MDL NO. 16-2738 (MAS) (RLS)

THIS DOCUMENT RELATES TO ALL CASES

THIRD AMENDED RULE 26 EXPERT
REPORT OF JUDITH WOLF, MD



Judith Wolf, MD

Date: May 28, 2024

I. BIOGRAPHY AND QUALIFICATIONS

I am a board certified gynecologic oncologist, a physician specializing in the care of women with cancer with more than thirty years experience. I attended medical school at Northeast Ohio Universities College of Medicine and then moved to Texas where I completed residency at the University of Texas San Antonio and fellowship at MD Anderson Cancer Center where I remained on faculty for more than twenty years as Professor in the Department of Gynecologic Oncology. My area of expertise is ovarian cancer - diagnosis, research, treatment, and patient advocacy.

I have authored or co-authored over 100 peer-reviewed research articles and was the principal investigator or co-investigator for eleven research grants related to gynecologic cancers. Additionally, I have served as the principal investigator, co-principal investigator, or collaborator on numerous protocols, and have presented at more than 50 conferences, as well as at numerous scientific exhibitions and seminars. The majority of these have dealt with some aspect of ovarian cancer.

My research began when I was a fellow in gynecologic oncology. In addition to two years of clinical training, I spent two years working in the lab and getting my master's degree in biomedical science from The University of Texas School of Biomedical Sciences in Houston. My research as a graduate student was in investigating targets for therapy in ovarian cancer. One of these led to a phase I Clinical trial for women with ovarian cancer using a targeted therapy. This trial was part of a larger National Cancer Institute (NCI) grant. After completing training, I maintained a research lab for over 10 years, investigating gene therapy for the treatment of both ovarian and cervical cancer. My laboratory research in ovarian cancer led to a Clinical trial of gene therapy for women with ovarian cancer. Being able to see the long road it takes to bring new therapies from the lab to clinic fostered my continued interest in clinical trials and led me to become involved in both investigator initiated and NCI cooperative group clinical trials - Phase II and III trials of new therapies for ovarian cancer.

Throughout my tenure as a Professor at MD Anderson Cancer Center, I was recruited to join the biomedical industry. It wasn't until 2014, when Vermillion, a diagnostic company, recruited me as a Chief Medical Officer that I felt compelled to make a change in my career path. By this point in time, I had cared for hundreds of women with ovarian cancer, and saw the devastation this disease causes, with little improvement in the overall prognosis in more than twenty years. Working with a diagnostic company, focused on the early detection of ovarian cancer, seemed to me to be another way I could work to make a difference. While at Vermillion, I co-authored several publications, helped the company gain FDA clearance for their second-generation multiprotein biomarker assay for ovarian cancer detection and was integral in the company obtaining a \$7.5 million dollar grant from the State of Texas for ovarian cancer detection.

After two years at Vermillion, I was recruited by another small start-up diagnostic company, ProvistaDx, as Chief Medical Officer. ProvistaDx was using similar multi-protein assays (like Vermillion) but combining them with antibodies to try to detect both breast and ovarian cancer early. While at ProvistaDx, we published several articles in the breast cancer detection area. This

effort included their first publication setting forth this combined technology for ovarian cancer detection.

Working in these diagnostic companies exposed me to some of the intricacies of working in the biomedical industry and research from the viewpoint of a publicly traded company (Vermillion) and a small private start-up (ProvistaDx). Additionally, I learned much about the regulation of the biomedical industry.

In mid-2018, I left my company position to have more time to focus on my volunteer and advocacy work for women's health with a large focus on ovarian cancer. In the mid-1990s, I became involved with raising awareness and educating women about ovarian cancer through my work with the National Ovarian Cancer Coalition (NOCC), serving as a medical board member and as a governing board member, a position I have held for more twenty years. NOCC's mission is to raise awareness and educate women and their families about ovarian cancer. Additionally, I combined my love of running and passion for ovarian cancer to organize a charity 5K walk/run to raise awareness and research money for the Blanton/Davis Ovarian Cancer Research Program at MD Anderson Cancer Center. This race has been going on now for more than twenty-five years and has raised millions of dollars for ovarian cancer research.

In 2014, I became a member of the board of the Society for Women's Health Research which is a national nonprofit dedicated to promoting research on biological differences in disease and improving women's health. Additionally, I began working with Health Volunteers Overseas. I have volunteered in Vietnam, Honduras and Haiti working with physicians in these countries to train them to be better able to care for women with gynecologic cancers. I have worked with HVO for the past year and a half and currently head a project that trains young surgeons in Nepal to care for women with ovarian, cervical and uterine cancers. Some of this work has been paused since early 2020 because of the COVID-19 pandemic.

I continue to practice medicine as a Gynecologic Oncologist, treating women with ovarian cancer and other gynecologic malignancies in numerous medical centers around the country. I am recruited on a regular basis to serve in communities which are lacking gynecologic oncology care.

II. METHODOLOGY

I was asked to make a determination as to whether the genital use of talcum powder can cause ovarian cancer. I approached this issue in a similar way and with the same rigor that I would use in my professional practice, both clinically and in research. This is an exercise I have used regularly throughout my thirty plus year career. I reviewed extensive medical and scientific literature (including epidemiological, animal, mechanistic studies, and reviews on all relevant topics). I also researched publicly available information related to talcum powder products, their safety, and their association with ovarian cancer. Many of these sources were obtained through articles and references from my personal library of journals, textbooks, as well as PubMed searches on relevant topics. Additional relevant literature, documents, and testimony were provided by the attorneys working on this case. I also requested additional information on various relevant issues when appropriate.

In doing this research, I applied the same standards that I use in clinical medicine to consider the reliability and validity of the medical and scientific literature, assessing the evidence according to the strengths and weaknesses of the study under review. I considered an extensive body of relevant literature, without regard to the nature of the specific findings. I based the opinions provided in this report using a weight of the evidence methodology in the context of Bradford Hill concepts.

III. OVERVIEW OF OVARIAN CANCER

Ovarian cancer is a group of malignancies that are believed to begin in ovarian or fallopian tube tissue. There are three groups of cancers based on the cell type from which they arise - germ cell, stromal, and epithelial cancers. Epithelial cancers (EOC) account for the vast majority of ovarian cancers (greater than 90%) and are further subdivided based on the microscopic characteristics of the cells. These subtypes include serous, endometrioid, clear cell, mucinous, undifferentiated or mixed. Of these, serous is by far the most common and accounts for 70% of EOC. Epithelial ovarian cancers are those that are associated with talcum powder products.

Epithelial carcinoma of the ovary, fallopian tube, and peritoneum are usually considered as a single entity due to their common clinical behavior, risk factors, and pathogenesis. Over the past decade, research has found that many serous carcinomas of the ovary may begin in the cells that line the distal portion of the fallopian tube. These cells then leak, drip, or “escape” from the tube and the ovary (which is next to the tube) or the peritoneum (the layer that lines the inside of the abdomen and pelvis). (Levanon 2008, Chen et al. 2017; Singh et al. 2016; Soong et al. 2018). Cancers that clinically appear to arise from the fallopian tube, ovary or peritoneum have the same microscopic appearance, pattern of spread (throughout the pelvis and abdomen), and response to treatment. This information is consistent with the role of talcum powder in cancer development.

Ovarian cancer is a relatively rare cancer. The American Cancer Society estimates in 2023, 19,710 new cases of ovarian cancer compared to 300,590 new cases of breast cancer.¹ There is no screening for ovarian cancer and symptoms are vague. This presentation leads to late diagnosis for more than 75% of patients. Because of these factors, ovarian cancer is the deadliest gynecologic malignancy in the U.S. Seventy to seventy-five percent of women with advanced stage EOC die from their disease, usually from bowel obstruction, following years of chemotherapy treatment.

The National Cancer Institute defines a risk factor as something that increases the chances of developing a disease. Associations can occur that are not actually linked with a disease. A causative risk factor is one that increases the chances of developing a disease by means of a known or predictable mechanism. In other words, it is more than a mere association. (Vineis 2017). As a physician, I use the terms risk factor and contributing cause interchangeably when the known or predictable mechanism for the effect is plausible.

The most significant risk factors associated with ovarian cancer are inherited susceptibility genes, primarily BRCA1, BRCA2, and the mismatch repair genes (associated with Lynch syndrome). BRCA mutations account for 75% of all hereditary ovarian cancers. A woman with BRCA1 gene

¹ <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2023/2023-cancer-facts-and-figures.pdf>.

mutation has a 39-46% lifetime risk of developing ovarian cancer; a woman with BRCA2 gene mutation has an 11-27% lifetime risk of developing ovarian cancer. (Ring et al. 2017). It is estimated that these hereditary gene mutations account for 10-15% of all ovarian cancer and 75% of all hereditary ovarian cancers. (Lancaster et al. 2015). It is important to distinguish these inherited gene mutations from induced mutations caused by inflammation or environmental insults. Women with a genetic predisposition to developing ovarian cancer are still subject to other environmental and reproductive risk factors.

In addition to talc and asbestos exposure, other risk factors that have been linked to EOC include increasing age, nulliparity, infertility, endometriosis, obesity, polycystic ovarian syndrome, use of an intrauterine device, history of pelvic inflammatory disease, and cigarette smoking (for mucinous carcinoma). Protective factors (associated with a decreased risk of EOC) include previous pregnancy, history of breastfeeding, oral contraceptives, and tubal ligation. (Hunn and Rodriguez 2012; Wu 2015; IOM 2016; Mallen, Townsend, and Tworoger 2018; Park et al. 2018; Gentry-Maharaj et al. 2018; Lheureux et al. 2019). It is important to note that risk factors can interact with each other or act independently. They can act in a cumulative, additive, and/or synergistic fashion. (Wu et al. 2018; Vitonis et al. 2011; e.g., Phung et al. 2022). For example, Phung et al. (2022) examined the effect of well-established ovarian cancer risk factors in women with and without endometriosis. The pooled analysis of 9 case-controlled studies in the Ovarian Cancer Association Consortium demonstrated that there was a greater increased risk of ovarian cancer with genital talc use in women with endometriosis (OR 1.38, 95% CI 1.04-1.84) versus those without endometriosis (OR 1.12, 95% CI 1.01-1.25).

Because cancer is not caused by a single genetic abnormality, ovarian cancer development is multifactorial. For example, not everyone who has an inherited BRCA mutation develops ovarian cancer, and not everyone who gets ovarian cancer has an inherited BRCA mutation. This was recognized as early as 1971 when Knudson published his “two-hit” hypothesis of carcinogenesis. (Knudson 1971).

Talcum powder dusting is often referred to as a “lifestyle factor”. There are no medical benefits; any risk, particularly a risk of something as devastating and deadly as ovarian cancer, is unacceptable. Because of this, I advise all my patients not to use talcum powder products or to stop using them if they are already doing so.

Most women with EOC present with pelvic or abdominal pain, bloating, and/or gastrointestinal symptoms. Diagnosis is based upon pathologic evaluation of tissue. Knowledge and evaluation of the pathology of ovarian cancer is part of every gynecologic oncologist’s training and experience. Staging is surgical. In a patient with advanced stage ovarian cancer (stage 3 and 4), the cancer is spread throughout the abdomen and pelvis with typically thousands of tumor nodules covering the surface of all internal organs, along with several liters of fluid containing cancer cells (ascites).

Treatment for ovarian cancer is a combination of surgery and chemotherapy. Most women with advanced disease obtain 1-2 years of remission after treatment, and then their cancer recurs. Once ovarian cancer recurs, it is not curable, and most patients spend the remainder of their life on chemotherapy in an attempt to extend their life spans and minimize their often severe symptoms.

IV. HISTORICAL BACKGROUND OF TALC

Johnson & Johnson's baby powder was introduced to consumers in 1894. (Guowitz 2007).

In the late 1940s and early 1950s, there were numerous articles (including at least one from Johnson & Johnson's own lab) describing the inflammatory properties of talc when introduced into the peritoneal cavity experimentally or through surgical gloves and the relative safety of starch products in the same setting. (Eberl and George 1948; Graham and Jenkins 1952). In 1953, Johnson & Johnson submitted a patent application for a "non-irritating" starch-based dusting powder due to the severe postoperative complications and strong inflammatory reaction frequently caused by talc. (Caldwell et al. 1953). In 1967, the association between asbestos and ovarian cancer was reported (J. Graham and Graham 1967).

Henderson first identified talc particles deep in ovarian tissue in 1971. (Henderson et al. 1971). Dr. Woodruff and colleagues at Johns Hopkins began raising awareness regarding environmental toxins like talc as etiologic factors in the pathogenesis of ovarian cancer in the early 1970s. (Parmley and Woodruff 1974).

In 1979, Longo and Young cautioned the cosmetic industry regarding the dangers of talc in *The Lancet*: "Epidemiological, experimental, and clinical data seem to link asbestos and talc with ovarian cancer. Direct passage of talc or asbestos-contaminated talc through the female reproductive tract to the ovarian surface may play an aetiological role. Further systematic evaluation of talc and asbestos as ovarian carcinogens is needed. What is disturbing is that a consultant to the cosmetic industry feels that further research on the biological effects of talc 'merits little priority.'" (D. L. Longo and Young 1979). The first epidemiologic study on the association between talc and ovarian cancer was published in 1982. (Cramer et al. 1982).

Between 1992 and 1995, concerns were raised in the medical literature regarding risks, including ovarian cancer, of talc on condoms. (e.g., Kang, Griffin, and Ellis 1992; Kasper and Chandler 1995). In 1995, the condom industry voluntarily agreed to stop dusting condoms with talc due to ovarian cancer concerns. ("PCPC_MDL00062175" 1999; McCullough 1996). Recommendations regarding the use of talcum powder on diaphragms were also discontinued in the late 1990s. In 1998, Janssen, a subsidiary of Johnson & Johnson, changed the warning on its All-Flex Diaphragm to state "Powders should not be used with the diaphragm."² Although the inflammatory properties of powder from surgical gloves were known for decades, the FDA only banned its use in 2016. (Federal Register / Vol. 81, No. 243).

V. EPIDEMIOLOGY

Since the early 1980's, there have been numerous epidemiological studies evaluating the risk of ovarian cancer with talcum powder usage. To the present time, there are over 25 case-control studies, three prospective cohort studies, two pooled analyses, and ten meta-analyses. I assessed all of these studies.

² Janssen sold the Ortho diaphragms beginning in the 1960s. The 1962 instructions stated, "Dust diaphragm when dry with talcum powder and return it to the original container." ("Pltf_MISC_00000272 (JANSSEN-000001-19)" 1962).

A case-control study is designed to help determine if an exposure is associated with an outcome, in this case ovarian cancer. First, researchers identify women with and without ovarian cancer - cases and controls. Then they look back in time to learn which subjects in each group had talcum powder exposure(s), comparing the frequency of the exposure in the case group to the control group.

A case-control study is always retrospective because it starts with an outcome then traces it back to investigate exposures. Advantages of case-control studies are that they are comparatively efficient, less expensive, and easier to perform. Potential weaknesses include selection bias, (because they are not randomized) and recall bias. Case-control studies are particularly appropriate for uncommon diseases, like ovarian cancer, in which a very large cohort would be required to accumulate enough cases for analysis. (Narod 2016).

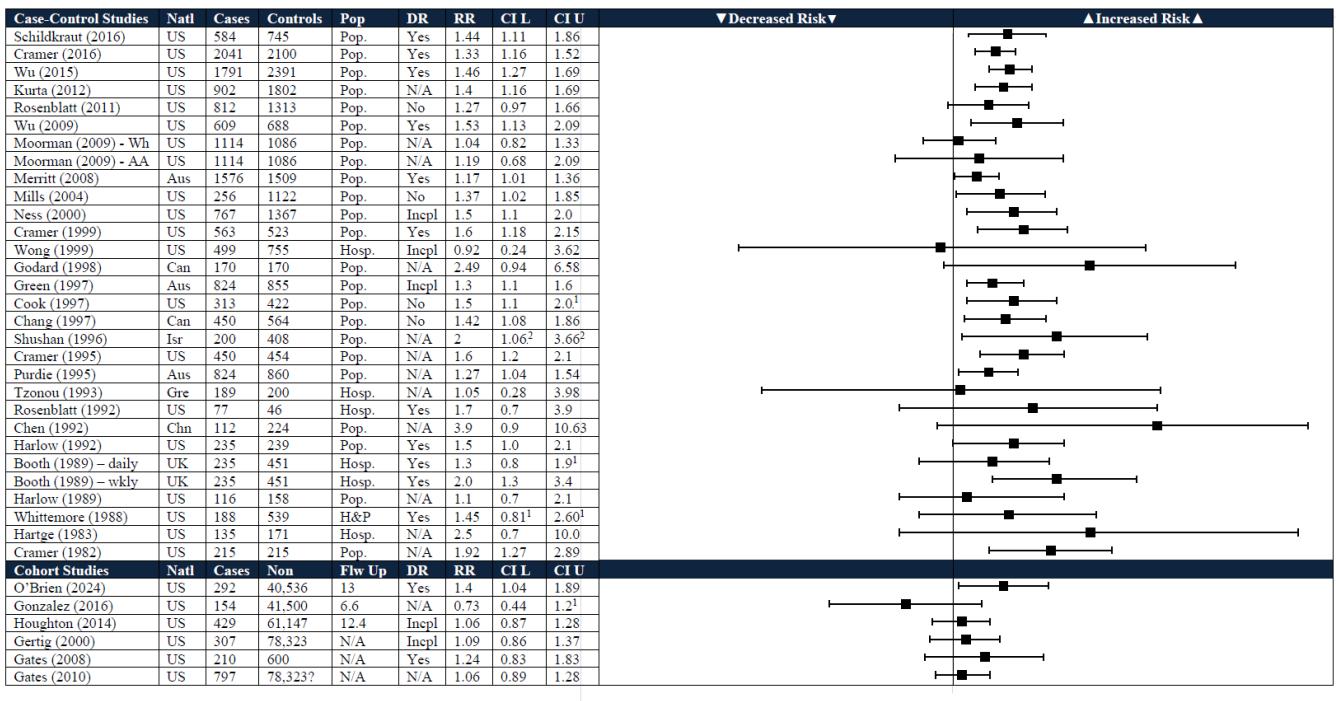
A cohort study follows a group of people with defined characteristics, such as talcum powder exposure, and who are followed to determine incidence of an outcome, in this case development of ovarian cancer. Cohort studies can be retrospective or prospective. They can calculate rates of disease in exposed and unexposed individuals for multiple outcomes over time. Potential disadvantages of cohort studies include the requirement of large number of subjects for rare exposures and outcomes and long duration of follow up for certain conditions. (Song et al. 2010). These disadvantages apply to the study of talc and ovarian cancer. Narod estimated that, for a cohort study to be properly powered to accurately predict the risk associated with talc use and ovarian cancer, as many as 200,000 women may be necessary. (Narod 2016).

A meta-analysis combines the results from previous studies to derive conclusions from a larger set of data. Outcomes from a meta-analysis may include a more precise estimate of the effect of treatment or exposure (talcum powder) than any individual study contributing to the pooled analysis. (Haidich (2010). A meta-analysis weights the strengths of the studies before combining the data, unlike a pooled study. A meta-analysis can be especially useful to review a complex, sometimes conflicting body of literature.

A randomized control trial, in which participants are divided by chance into separate groups to compare different interventions, is considered the gold standard in some research situations. However, it would be unethical and impractical to conduct a prospective randomized control clinical trial to compare the outcomes of women who did and did not use genital talcum powder because of its known carcinogenic potential.

For this project, I reviewed all epidemiological studies related to talcum powder and ovarian cancer, but concentrated on the cohort studies, the meta-analyses, and more recent high-quality case-control studies. I critically analyzed factors such as study design, journal quality, number of subjects, length of follow-up, and potential biases. The following forest plots, prepared at the direction of Anne McTiernan, MD, PhD, are helpful presentations of relevant data from epidemiological studies.

Figure 2: Case-Control and Cohort Studies

¹ Corrected data-point from study text (report figure: Cook 1997 CI Upper 2.3; Gonzalez CI Upper 1.21; Booth 1989 CI Upper 1.0; Whittemore CI p=0.06).² Corrected data-point from defense expert report(s) (report figure: p=0.04).

Case-Control Studies

There are numerous case-control studies. Overall, the case-control studies are consistent showing a 30-50% increase in risk of ovarian cancer with talcum powder use. I found the most recent ones to be the most useful, based on their size and quality of design. Several are summarized below: A study by Wu published in 2015, evaluated 1701 women with EOC in California. The conclusion of this study found that talc significantly increased the risk of ovarian cancer – 40% in whites, 20% in Hispanics, and 56% (not statistically significant) in African Americans. The number of African Americans with ovarian cancer was only 128 and may account for the non-significant increase. (Wu et al. 2015).

Cramer published a recent case-control study of nearly 4,000 women in Massachusetts and New Hampshire with ovarian cancer and found that genital use of talcum powder, either alone or in combination with body use, was associated with a statistically significant elevated epithelial ovarian cancer risk (OR 1.33). Risk increased with frequency and duration of use. Talcum powder use increased risk for serous and endometrioid tumors with the dose response most apparent for invasive serous cancer. (Cramer et al. 2016).

A multi-center study sponsored by National Cancer Institute of epithelial ovarian cancer in African-American women, a group with a high prevalence of talcum powder use, determined that regular genital powder use was associated with an increased risk of epithelial ovarian cancer (OR 1.44). A dose-response relationship was found for duration of use and number of lifetime applications ($P < 0.05$). Additionally, talcum powder use was common (62.8% of cases and 52.9% of controls). (Schildkraut et al. 2016).

Cohort Studies

The Nurses' Health Study (NHS I) is a prospective study of 121,700 nurses who were aged 30-55 years at enrollment in 1976 and followed through 1996 at the time of the publication. In the NHS, talcum powder use was ascertained once in 1982, the same year as the first case-control study showing an association of talc use with ovarian cancer. (Cramer et al. 1982). The follow up period for this study was 12.9 years. The study concluded there was no overall association with talc "ever use" and epithelial ovarian cancer. However, there was a statistically significant increased risk of invasive serous ovarian cancer (40%) that was higher with more frequent talcum powder use. The short period of follow up may not account for all ovarian cancer cases due to latency considerations between talcum powder usage and the development of ovarian cancer. (Gertig et al. 2000). A second report of the Nurses' Health Study (NHS II) in 2010 did not find a statistically significant increased risk with talcum powder usage, either epithelial cancer as a whole or serous subtype. (Gates et al. 2010).

The Women's Health Initiative (WHI) enrolled 93,676 women from 1993-1998. Women were eligible if they were aged 50 to 79 (mean 63.3 years) at enrollment and postmenopausal. Mean follow-up was 12.2 years. Use of powder on the genitals was associated with 12% increased risk of ovarian cancer, though this was not statistically significant. Limitations of this study include lack of information regarding oophorectomy and recall bias regarding history of talc "ever use". Additionally, the short follow-up may not account for all cases of ovarian cancer. Information regarding the frequency or duration of powder usage was not obtained. (Houghton et al. 2014).

The Sister Study (2003-2009) followed 50,884 women in the US and Puerto Rico who had a sister diagnosed with breast cancer. At enrollment, participants were asked about douching and talcum powder use in the previous twelve months. During follow-up (median 6.6 years) 154 women reported a diagnosis of ovarian cancer but only seventeen of those reported talc use. The authors determined that there was little association between baseline talcum powder use and subsequent ovarian cancer. Douching at baseline, more common in talc users, was associated with increased risk. All ovarian cancers were grouped together. Limitations of this original study include: 1) talc use was only obtained at baseline and was uncommon (analysis was based on only 17 cases), 2) no histologic information was obtained, so it is impossible to analyze relationship to serous subtype, 3) no risk elevation has ever been reported with dusting of diaphragm, cervical cap, or sanitary napkins, and 4) the short follow-up fails to account for the latency period. (Gonzalez et al. 2016).

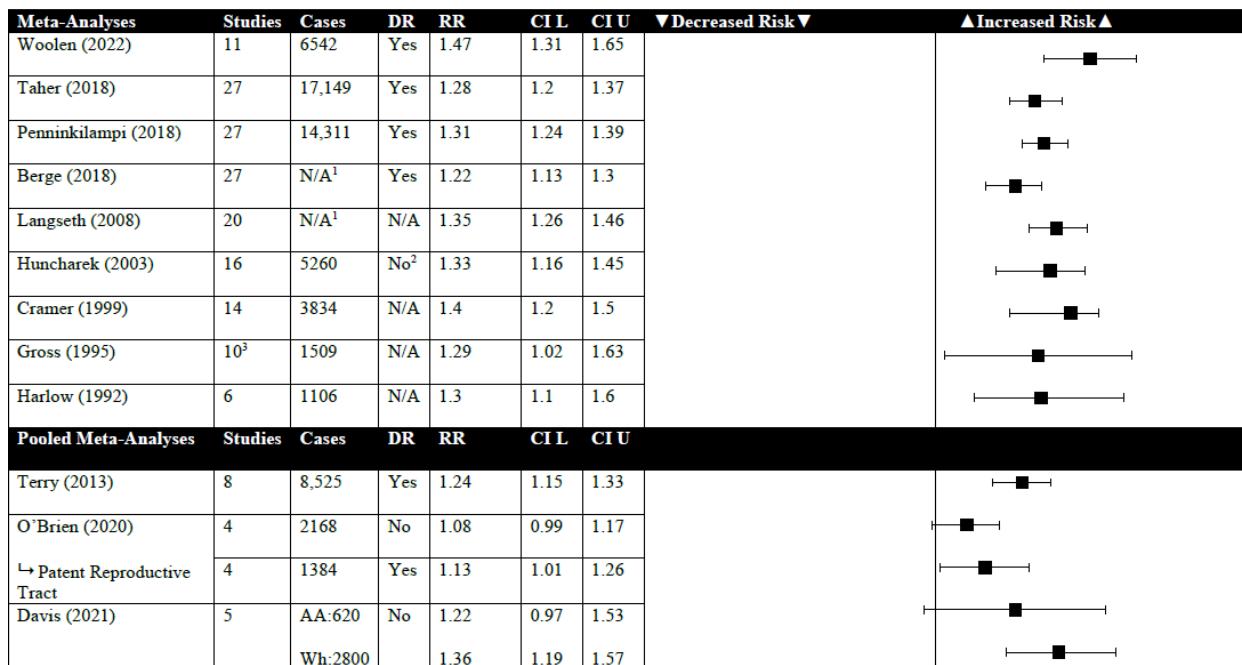
All of the original cohort studies are limited by lack of power, failure to make the appropriate queries, selection bias, and short follow-up.

Fortunately, the Sister Study has been updated with more detailed information about the use of douche and genital talc, which was obtained in the fourth follow-up questionnaire (2017-2019). (O'Brien, et al. J Clin Oncol 00:1-15 (2024)). The authors used models that adjusted for exposure misclassification, and genital talc use was positively associated with ovarian cancer (HR range, 1.17-3.34). In women who were frequent users, the hazard ratio was 1.81 (1.29 to 2.53), and in women who were long-term genital talc users, the hazard ratio was 2.01 (1.39 to 2.91). Genital use of talcum powder by women during their 20s and 30s found the greatest increased risk. This study considered recall bias and found an increased risk of ovarian cancer both with and without correction for it.

This study was accompanied by an editorial by Harris et al. (2024), also in the *Journal of Clinical Oncology*, with a takeaway stating, “Given that genital powder use and douching are modifiable exposures potentially associated with a highly fatal disease, these data suggest that people at risk for ovarian cancer, particularly those in their 20s and 30s, should be made aware of the potential risks.” The editorial additionally states that “Primary care providers and gynecologists should consider addressing routine genital powder use and douching with their patients in a manner that addresses potential risks....”

The same day this paper was published, the American Society of Clinical Oncology in *ASCO Perspective* addressed this study, stating, ““This study underscores the potential risks associated with intimate care products, particularly genital talc. The evidence adds to a growing body of literature that suggests such products could contribute to an increased risk of ovarian cancer, especially among frequent users and those using these products in their 20s and 30s,’ said ASCO Expert Fumiko Chino, MD, Radiation Oncologist at Memorial Sloan Kettering Cancer. ‘Despite challenges in assessing exposure history and biases inherent in retrospective data, our findings are robust, showing a consistent association between genital talc use and ovarian cancer,’ said lead study author Katie M. O’Brien, Ph.D., researcher at the Epidemiology Branch of the National Institute of Environmental Health Sciences. ‘This study leverages detailed lifetime exposure histories, and the unique design of the Sister Study, to provide more reliable evidence that supports a potential association between long-term and frequent genital talc use and ovarian cancer.”

Meta-Analyses and Pooled Studies (All Ovarian)



Meta-Analyses and Pooled Studies

Five meta-analyses addressed the relationship between genital talcum powder use and ovarian cancer and each of these found a statistically significant relationship. (Berge, 2018, Penninkilampi 2018, Taher 2019, Davis 2021, Woolen 2022). The comprehensive meta-analysis by Penninkilampi and Eslick, published in 2018, included 24 case-control (13,421 cases) and three cohort studies (890 cases). The authors found that “any” perineal talc use was associated with an increased risk of ovarian cancer (OR = 1.31; 95% CI = 1.24, 1.39). More than 3600 lifetime applications (OR = 1.42; 95% CI 1.25, 1.39) were slightly more associated with ovarian cancer than <3600 (OR = 1.32; 95% CI = 1.15, 1.50). An association with “ever use” of talc was found in case-control studies (OR = 1.35; 95% CI = 1.27, 1.42), but not cohort studies (OR 1.06; 95% CI = 0.90, 1.25). However, cohort studies did find an association between talc use and invasive serous ovarian cancer (OR = 1.25; 95% CI = 1.01, 1.55). The authors stated that case-control studies are preferred in this situation because statistical power is easier to obtain with the larger number of ovarian cancer cases and controls and the lengthy follow-up necessary for a prospective study is not required. I agree. The authors determined that perineal talc use is associated with a 24%–39% increased risk of ovarian cancer that is suggestive of a causal association. (Penninkilampi and Eslick 2018).

Of note, the Penninkilampi meta-analysis was identified as one of the “best articles” of 2018 on ovarian cancer in *Obstetrics and Gynecology*, the journal published by the American College of Obstetricians and Gynecologists. (Wright 2018).

In addition to Penninkilampi, the four other recent meta-analyses described similar findings. Berge determined that the summary relative risk (RR) for ever use of genital talc and ovarian cancer was 1.22 [95% confidence interval (CI): 1.13–1.30]. (Berge 2018). Taher, a meta-analysis commissioned by Health Canada, also found a statistically significant positive association between perineal use of talc powder and ovarian cancer [OR: 1.28 (95% confidence interval (CI): 1.20 - 1.37)]. (Taher 2019).

Davis (2021) focused on African American women as genital talcum powder use is more common in this group. Using data from five studies conducted by the Ovarian Cancer in Women of African Ancestry Consortium, the investigators found among African American women an increased risk with genital talcum powder use and ovarian cancer (OR = 1.22; 95% CI: 0.97-1.53) and for high grade serous (OR = 1.31; 95% CI: 1.01-1.71). For white women, the odds ratio for ever use of talcum powder and ovarian cancer was 1.36 (95% CI: 1.19-1.57) and for high grade serous 1.33 (95% CI: 1.12-1.56). For all women, the results were an increased risk of 32% both for all ovarian cancer and high grade serous, (OR = 1.32; 95% CI: 1.17-1.48) and (OR = 1.32; 95% CI: 1.15-1.51) respectively.

Woolen (2022), a systematic review and meta-analysis, found a statistically significant increased risk of ovarian cancer with frequent use of perineal talcum powder (defined as \geq 2 times per week (OR = 1.47; 95%, CI 1.31-1.65). Woolen reported data regarding daily use from the Nurse's Health Study (NHS) which found a statistically significant increased risk in all women (1.27, 95%, CI 1.09-1.49) and in women with patent fallopian tubes (1.40, 95%, CI 1.17-1.68).

In addition to these meta-analyses, O'Brien published a pooled study in 2020. This study pooled data from cohort studies: Nurse's Health Study I and II (NHS), Women's Health Initiative (WHI), and the Sisters Study. (O'Brien 2020, O'Brien Supp. E-Tables 2020, Gossett 2020). This study included 252,745 subjects; 1884 developed confirmed ovarian cancer. The information obtained in these studies on talcum powder usage patterns was different in each of these cohorts. However, the authors attempted to standardize these discrepancies by combining groups across the studies. The authors acknowledged the direct physical pathway between exposure of talcum powder on the perineum and the fallopian tubes and ovaries.

The overall relative risk for "ever use" versus "never use" of genital talcum powder was 1.08 (CI 0.99-1.17). However, significantly elevated risk was found in women with patent reproductive tracts (RR 1.13; CI 1.01-1.26). In addition, a statistically significant increased risk was noted in frequent users (at least weekly) and women who had previously used hormone therapy. There were limitations and deficiencies in this study that are discussed in Letters to the Editor. (Cramer & Harlow, Letters to the Editor with Reply, 2020).

Summary of Epidemiological Evidence

When looking at epidemiological studies in their totality, the data demonstrates a consistent, replicated, and statistically significant increased risk of developing epithelial ovarian cancer with perineal talcum powder use. Invasive serous carcinoma is the most commonly associated histologic subtype. The risk elevation is 20-60%. This risk is stable among case-control studies, one cohort study, and all meta-analyses/pooled analyses over several decades. Recall and confounding bias in case-control studies appear to have minimal impact. (Penninkilampi and Eslick 2018; Langseth et al. 2008). There appears to be no significant publication bias. (Berge et

al. 2017; Penninkilampi and Eslick 2018). Meta-analysis is the most reliable and scientifically valid epidemiological methodology to evaluate the association of talcum powder usage with ovarian cancer risk.

VI. ASBESTOS, FIBROUS TALC, AND OTHER CONSTITUENTS OF TALCUM POWDER

Asbestos is one of the most potent carcinogens known. All forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite) are carcinogenic to humans. (IARC 2012) The conclusions reached by International Agency for Research on Cancer (IARC) about asbestos and its carcinogenic risks apply to these six types of asbestos wherever they are found and includes talc containing asbestos fibers (fibrous talc or talc fibers). (IARC 2012) Asbestos was first linked to pulmonary mesothelioma in 1935 (Gloyn 1935) and has been known to be an etiologic factor for ovarian cancer since 1965. (Graham and Graham 1967).

According to IARC, asbestos causes mesothelioma of the lung, larynx, and ovary. Based on multiple positive cohort mortality studies of women with heavy occupational exposure to asbestos, IARC's Working Group determined there is a causal association between asbestos exposure and ovarian cancer. The IARC 2012 Monograph on asbestos and fibrous talc states, "consumer products (e.g., cosmetics, pharmaceuticals) are the primary source of exposure to talc for the general population. Inhalation and dermal contact (i.e., through perineal application of talcum powders) are the primary routes of exposure." (IARC 2012).

A recent meta-analysis by Nowak (2021) found that there was a significant increased risk in ovarian cancer following occupational asbestos exposure (OR=1.88 (1.47, 2.39) and concluded that asbestos exposure is a cause of ovarian cancer. The EPA has also concluded that ovarian cancer is a health effect caused by exposure to asbestos. (EPA, Fed. Reg., Vol. 88, No. 141 (2023).

The scientific literature demonstrates that talc can contain asbestos and fibrous talc. (Cralley et al. 1968; Rohl et al. 1976; Lockey 1981; Paoletti et al. 1984; Blount 1991; Werner 1982). Blount (1991), Johnson & Johnson internal testing results and documents, and testing results of Dr. William Longo and Dr. Mark A. Rigler have demonstrated that talcum powder products, including Johnson's Baby Powder and Shower to Shower, may contain asbestos. (Blount 1991; "Deposition of Alice M. Blount, Ph.D., Circuit Court of the City of St. Louis State of Missouri, Case No.: 1522-CC10417-01" 2018; "Exhibit 28, Deposition of John Hopkins, Ph.D., In Re: Talcum Powder Prod. Liab. Litig., MDL No. 2378" 2018; "Exhibit 47, Deposition of Julie Pier, In Re: Talcum Powder Prod. Liab. Litig., MDL 2738" 2018; Longo & Rigler Expert Report (Feb. 2, 2019). Drs. Longo and Rigler found that 44 of 65 (68%) historical samples of Johnson's Baby Powder and Shower to Shower were positive for amphibole asbestos. These historical samples originated in the 1960s through the early 2000s. They found that 55 of 56 of these (98%) historical samples contained fibrous talc.

In October 2019, the FDA reported the results of testing conducted by AMA Analytical Services, Inc. on a bottle of Johnson's Baby Powder purchased in 2018. AMA identified chrysotile asbestos and talc fibers. These findings provide further data demonstrating the presence of asbestos and talc fibers in talcum powder products. (AMA Certificate of Analysis, October 11, 2019, Owen 2019).

Asbestos fibers and talc fibers exposure are known to cause ovarian cancer; their presence in Johnson & Johnson talcum powder products contributes to the carcinogenicity of the products through an established mechanism of inflammation, DNA damage, and genetic alterations. Asbestos and talc fibers may directly induce DNA damage mediated by reactive oxygen species. Fibers have also been shown to physically interfere with the mitotic apparatus, which may result in aneuploidy or polyploidy, and specific chromosomal alterations characteristic of asbestos-related cancer. In addition, persistent inflammation and macrophage activation can secondarily generate additional reactive oxygen species and reactive nitrogen species that can indirectly induce genotoxicity in addition to activation of intracellular signaling pathways, resistance to apoptosis, stimulation of cell proliferation, induction of epigenetic alterations, and activation of oncogenes/inactivation of tumor suppressor genes. (IARC 2012; Kane et al. 1996; Mossman 2018; Shukla et al. 2009; M. C. Jaurand 1997, 1989; M. Jaurand 1991).

In addition to asbestos and fibrous talc, talcum powder products have been shown to contain nickel, chromium, and cobalt. ("Exhibit 47, Deposition of Julie Pier, In Re: Talcum Powder Prod. Liab. Litig., MDL 2738" 2018). Nickel and chromium are Group 1 carcinogens according to IARC. Cobalt is a Group 2b (or possible carcinogen) according to IARC. The inflammatory mechanism for carcinogenesis for these metals is similar to that described for asbestos, fibrous talc, and platy talc.

I have also seen the list of "fragrance chemicals" added to Johnson's Baby Powder and Shower to Shower products, as well as the expert report of Dr. Michael Crowley. Many of these chemicals are known to be irritants, toxins, and carcinogens. Some have been shown to be harmful to the reproductive organs and function. These chemicals would be expected to accompany the talcum powder as it migrates or is transported through the genital tract to the fallopian tubes and ovaries. At least some of these chemicals would also be expected to be absorbed through the vaginal mucosa. These chemicals likely contribute to the inflammatory properties, toxicity, and carcinogenicity of these talcum powder products.

The presence of these constituents provides additional support for the mechanism by which Johnson's Baby Powder and Shower to Shower cause ovarian cancer, as demonstrated in the epidemiological literature.

VII. MIGRATION AND TRANSPORT OF TALC THROUGH THE GENITAL TRACT

In the adult female, the peritoneal cavity communicates with the outside via the fallopian tubes, uterus, and vagina. It is an open system (Netter, Crum, Blaustein). This is apparent in literature describing normal female external genitalia. (Lloyd 2005). MRI evidence also demonstrates an open vagina even in its nondistended state. (Barnhart 2006). As such it is universally accepted in the gynecologic community that substances migrate and/or be transported in both directions.

Evidence to support the migration/transport of talc particles and fibers includes, but is not limited to:

1. Sperm: Sperm move more quickly through the genital tract than would be predicted from innate motility, indicating a transport mechanism. In addition, dead sperm and inanimate sperm particles (lacking flagella) are efficiently transported upwards through the uterus

and tubes. (Jones and Lopez 2006). This process involves directed uterine contractility that has been confirmed through research of intrauterine pressure measurements. (Kissler et al. 2004).

2. Carbon particles: Inert carbon particles were placed in the posterior vaginal fornix and observed in the fallopian tubes 28 and 34 minutes later (2 out of 3 patients tested). This research confirmed that sperm motility is not the chief factor in transport and that contractions of the uterus are likely involved in process of migration/transport of particles through the genital tract. (Egli and Newton 1961).
3. Retrograde menstruation: The transport of menstrual flow into the peritoneal cavity was first proposed by Sampson in 1927 and is now well-established as the mechanism for endometriosis initiation. The prevalence of retrograde menstruation has been described in 90% of investigated women. (Blumenkrantz et al. 1981; Halme et al. 1984).
4. Particulate radioactive material: Particulate radioactive material was placed in the posterior vaginal fornix. Twenty four hours later, radioactive material was present in the adnexa separate from the uterus in 2/3 of cases. The authors concluded that the transit of particles from the vagina to the peritoneal cavity and the ovaries “is probably the same for many chemical substances used for hygienic, cosmetic, or medicinal purposes, many of which may have potential carcinogenic or irritating properties . . . migration of certain chemical substances could play an important aetiological role in gynaecological diseases and especially in carcinoma of the ovary.” (Venter and Iturralde 1979).
5. Bathwater: Psooy in 2010 demonstrated that bathwater can become entrapped in the vagina in females with normal anatomy. (Psooy 2010).
6. “Uterine peristaltic pump”: Rapid and sustained sperm transport from the cervix to the fallopian tube is provided by uterine peristaltic contractions that can be visualized by vaginal sonography. (Kunz 1997; Zervomanoklakis et al. 2007).
7. Glove powder: Studies have demonstrated retrograde migration of starch after gynecological examination with powdered gloves. The authors concluded that: “Consequently, powder or any other potentially harmful substances that can migrate from the vagina should be avoided.” (Sjösten, Ellis, and Edelstam 2004).
8. Talc: Studies have documented the presence of talc particles in the adnexa, ovaries, and peritoneum. The authors of these studies have concluded that this occurs as a result of migration of talc particles from the vagina through the cervix, uterus, and fallopian tubes. (Henderson et al. 1971, 1979; D. W. Cramer 1999; Heller et al. 1996). Talc has also been noted in pelvic lymph nodes which could also occur through migration, absorption, or inhalation with transport through the lymphatic system. (Cramer et al. 2007). A follow-up to the 2007 study regarding the presence of talc in lymph nodes and other pelvic organs controls for contamination as a potential source of the talc particles seen. (McDonald 2019 AJCP).

The migration of particles, including talc, asbestos and other constituents of talcum powder products, from the perineum to the upper genital tract (tubes and ovaries) is a key element in the mechanism by which talcum powder products cause ovarian cancer. The evidence supporting this process is robust and universally accepted by the medical community.³ (FDA Citizens Petition response 2014). I have considered the limited evidence to the contrary and find it non-persuasive.

In addition to perineal application resulting in migration and transport of particles through the genital tract, inhalation of these particles is another recognized route of exposure. (IARC 2012; W. E. Longo, Rigler, and Egeland 2017; Steiling et al. 2018; Cramer et al. 2007). With either of these routes, talcum powder components can also be directly absorbed into the lymphatic system and bloodstream.

VIII. INFLAMMATION AND MOLECULAR BASIS FOR CARCINOGENESIS OF TALCUM POWDER PRODUCTS

The link between inflammation and cancer has been recognized since the 1800s. Inflammation and oxidative stress increase the risk of cancer, including ovarian cancer. It has been known since the 1940's that talc causes inflammation. (Eberl and George 1948).

There is an increased risk of malignancy with many inflammatory processes, including infection, autoimmune diseases, hypoxia, and chemical and physical agents (including talc and asbestos).

1. Virchow noted inflammatory cells (leukocytes) in neoplastic tissue as early as 1863.
2. Inflammation resulting from talcum powder use has been proposed as a potential mechanism for the association with EOC. (Ness 1999; Balkwill & Mantovani 2001; Phung et al. 2022).⁴
3. Both tumor cells and inflammatory cells produce cytokines and chemokines which can contribute to cancer growth and spread.
4. Cytokines from inflammation/oxidative stress can influence multiple steps of the neoplastic process: survival, growth, mutation, proliferation, differentiation, and movement of cells. (Balkwill and Mantovani 2001; Reuter et al. 2010; Crusz and Balkwill 2015; Kiraly et al. 2015; Fletcher et al. 2019). Below are examples of inflammatory cytokines and their influence on cancer:
 - a. Tumor necrosis factor (TNF) can induce reactive oxygen (nitric oxygen (NO)) which can cause DNA damage. DNA damage can also occur by inhibiting cytochrome p450.

³ FDA states that the “potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable.

⁴ Richard Zazenski, Director Product Safety for Luzenac, states in an email to Bill Ashton, on September 30, 2004: “I came across this paper this morning published in the April 2004 journal “Human Reproduction”, an official journal of the European Society for Human Reproduction and Embryology. It offers some compelling evidence **in support of the** ‘migration’ hypothesis. Combine this ‘evidence’ with the theory that talc deposition on the ovarian epithelium initiates epithelium inflammation – which leads to epithelium carcinogenesis – and you have a potential formula for NTP classifying talc as a causative agent in ovarian cancer.” (“IMERYS137677-IMERYS137690” 2004).

- b. Migration inhibitory factor (MIF) can inhibit the activity of p53 which is a tumor suppressor.
- c. IL-6, IL-1, IL-8 are all known to stimulate tumor cell proliferation and survival.
- d. Multiple inflammatory cytokines (TNF, IL-1, IL-6, TGF beta 1) can stimulate angiogenesis.
- e. TNF and IL-1 stimulate adhesion to promote invasion and metastasis of cancer cells.

5. Inflammation/oxidative stress affects all phases of cancer development and growth and is implicated in pathogenesis of ovarian cancer. This leads to decreased apoptosis and increased anaerobic metabolism. Anaerobic metabolism leads to an acidic state which facilitates cancer growth. (G. Saed 2017; G. M. Saed et al. 2010; Jiang et al. 2011; Shan and Liu 2009; Freedman et al. 2004).

6. Talcum powder causes inflammation/oxidative stress both *in vitro* and *in vivo* (in both animal and human tissues). (Eberl and George 1948; Graham and Jenkins 1952; Hamilton et al. 1984; Buz'Zard and Lau 2007; Shukla et al. 2009; Fletcher et al. 2019; Akhtar 2010, 2012; Mandarino et al. 2020; Emi et al. (2021); "NTP Toxicology and Carcinogenesis Studies of Talc (CAS No. 14807-96- 6) (NonAsbestiform) in F344/N.Rats and B6C3F1 Mice (Inhalation Studies)" 1993; Keskin et al. 2009).

7. Although the literature is still somewhat contradictory, aspirin and other non-steroidal anti-inflammatory drugs have been shown to prevent and treat certain types of cancer, particularly colorectal. (Trabert et al. 2019; Rayburn, Ezell, and Zhang 2009; Chan et al. 2005).

8. Fletcher et al. describes induction of gene point mutations after Johnson's Baby Powder exposure, corresponding to known single nucleotide polymorphisms (SNPs) in normal and ovarian cancer cells *in vitro*. These SNPs alter the activities of key oxidant enzymes and enhance the pro-oxidant state. This process of gene mutation is part of the carcinogenic cascade initiated by inflammation and oxidative stress. These results are consistent with other *in vitro* studies. (Shukla et al. 2009, Buz'Zard and Lau 2007, Akhtar et al. 2010, 2012; Mandarino et al. 2020; Emi et al. (2021). Harper 2023 reported cell proliferation, neoplastic transformation and p53 mutations when cells in culture were exposed to Johnson's Baby Powder.

9. In summary, inflammation/oxidative stress has been well established as a significant factor in the development of cancer, including epithelial ovarian cancer. Inflammation/oxidative stress facilitates cancer growth at multiple steps. A recent review article provides a comprehensive discussion of the role of inflammation in the initiation, development, progression, metastasis, and chemoresistance of EOC. This paper identifies talc exposure as one source of inflammation in the ovary and fimbria. (Savant 2018).

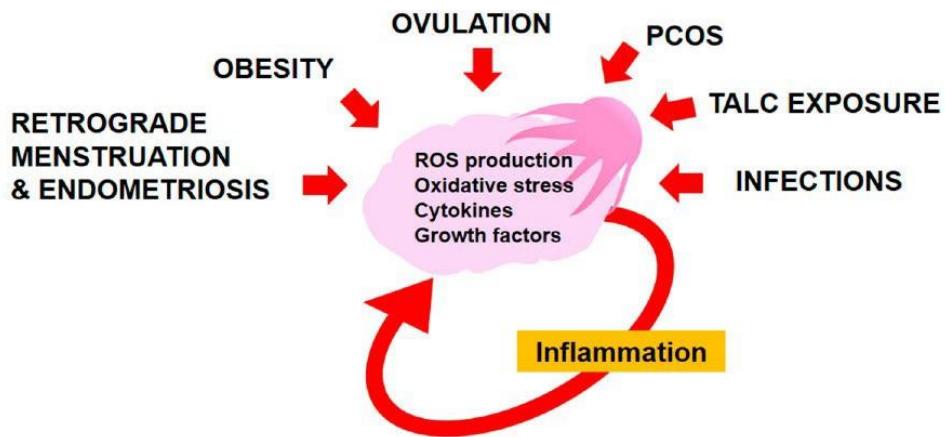


Figure 1. Sources of inflammation in the ovary and fimbriae. Ovulation, retrograde menstruation, endometriosis, infections, exposure to talc, Polycystic Ovarian Syndrome (PCOS), and obesity result in exposure of the ovary and fimbriae to reactive oxygen species (ROS), oxidative stress, cytokines, and growth factors, generating an inflammatory response that leads to additional production of ROS and cytokines in the ovary. Unresolved, chronic inflammation is a critical risk factor for tumor initiation.

(Savant 2018).

IX. CORNSTARCH

Since 1948 with a publication from Johnson & Johnson's own laboratory, it has been clear that starch is a safer alternative to talc for use on surgical gloves. Starch, unlike talc, is not an irritant and can be absorbed readily. (Eberl and George 1948).

A review paper by Whysner and Mohan in 2000 evaluated the available literature regarding the effects of cornstarch in the peritoneal cavity, comparing the potential risk of ovarian cancer with cornstarch versus talc. Unlike talc, the authors noted that 1) cornstarch is capable of being removed by physiologic processes from the peritoneal cavity, 2) cornstarch contains no asbestos, and 3) epidemiologic studies reviewed found no relationship between cornstarch powder use and ovarian cancer. The authors concluded that any increased risk for ovarian cancer as a result of peritoneal exposure to cornstarch was biologically implausible. (Whysner and Mohan 2000).

X. DETERMINING WHETHER A RISK FACTOR IS CAUSATIVE

Although Bradford Hill factors are primarily an epidemiologic tool, the general principles provide a framework for clinical doctors to assess whether diseases like cancer can be caused by a particular agent, condition, or practice. The Bradford Hill factors are not a formal checklist. These considerations are the same as those that I apply regularly, both in my clinical practice and research, and are similar to the principles of evidence- based medicine. (Brewster 2017 in DiSaia and Creasman, Fedak 2015).

The factors as described by Bradford Hill are:

1. Strength (effect size): A small association does not mean that there is not a causal effect, though the larger the association, the more likely that it is causal.
2. Consistency (reproducibility): Consistent findings observed by different persons in different places with different samples strengthens the likelihood of an effect.
3. Specificity: Causation is more likely if there is a specific disease with no other likely explanation. Most frequently used example is a specific bacterium causing a particular disease (e.g., *M. tuberculosis* causes TB and *T. pallidum* causes syphilis). The more specific an association between a factor and an effect is, the bigger the probability of a causal relationship, but this is not necessarily required.
4. Temporality (and Latency): The effect must occur after the cause (and if there is an expectant delay between the cause and expected effect, then the effect must occur after that delay).
5. Biological gradient (Dose-response): Greater exposure should generally lead to greater incidence of the effect. There may also be a minimum level of exposure necessary (threshold). As a general principle of pharmacology and toxicology, the likelihood of a response increases with longer and more frequent exposure to an agent (dosage). (Klaassen and Doull 2013).
6. Plausibility: A plausible mechanism between cause and effect is helpful (but Hill noted that knowledge of the mechanism can be limited by current knowledge). Knowledge and understanding of the biological mechanisms changes over time.
7. Coherence: Coherence between epidemiological and other research data/findings increases the likelihood of an effect. Coherence is the idea that an alleged association should not conflict with substantive knowledge that exists regarding the disease at issue.
8. Experiment: “Occasionally it is possible to appeal to experimental evidence”. This factor often refers to support from animal and clinical research with sound methodology. Has there been an attempt to collect data to analyze a cause and effect relationship? Do studies use controls when feasible? Are experiments reproducible? Are there ethical limitations?
9. Analogy: The effect of similar factors may be considered. All the rules relating to scientific methodology must be employed at each stage of the analogy. (Fedak et al. 2015).

I considered these aspects of a causal relationship in determining whether talcum powder products cause ovarian cancer.

Strength

Overall, the studies show a 1.3-1.4 odds ratio of increased risk of ovarian cancer among perineal talc users. A recent and most complete meta-analysis determined an odds ratio of 1.31 with any perineal talc use and the development of ovarian cancer. An association with ever use of talc was found in case-control studies (OR = 1.35) and in the newest cohort study publication (HR range = 1.17-3.34) when adjusted for exposure misclassification. Cohort studies also found an association between talc use and invasive serous type ovarian cancer. (Penninkilampi and Eslick 2018). If invasive serous ovarian cancer or frequent use is considered, the association is even stronger.

Strength is also supported when there are numerous studies with consistent findings as in the case of talcum powder and the association with ovarian cancer. In general, many of the studies are well conducted, numerous and consistent, making the strength of the association valid. When looking at causation of a relatively rare disease like ovarian cancer, this magnitude of risk is statistically and clinically significant and not unusual. With ovarian cancer, a disease which is difficult to diagnose and deadly, any preventable risk factor (talcum powder) should be deemed critically important and avoided.

Consistency

The magnitude of risk has been consistent over four decades, across various geographic populations and throughout the United States, Canada, and Australia. Results are generally consistent across case-control, meta-analysis, and pooled analysis studies. I deemed the consistency and replication of the studies to be important in my causation analysis.

Specificity

The most compelling disease associated with talcum powder use is epithelial ovarian cancer, therefore specificity for a disease is demonstrated. The most recent cohort publication also addressed specificity as there was no association between genital talc use and increased risk of uterine or breast cancer.

Temporality

Exposure to talcum powder and the resultant development of ovarian cancer meets the temporality consideration that the outcome follows the event. The average latency period between exposure to talc and diagnosis of ovarian cancer is at least twenty years. This is consistent with other cancers known to be caused by chemicals and/or toxins. (Purdie et al. 2003; Okada 2007).

Biologic Gradient (Dose-response)

Exposure is difficult to quantify with talcum powder applications with regard to how much is used, where it is concentrated, and how much actually reaches the tubes and ovaries; Many of the studies did not obtain the necessary information to evaluate dose response and lacked adequate power to assess dose-response accurately. Despite the lack of sufficient information in many studies, recent meta-analyses/pooled study and a case-control studies do show a dose response, using frequency and duration of use as parameters. (Penninkilampi and Eslick 2018; Cramer et al. 2016; Schildkraut et al. 2016; Terry et al. 2013; Wu et al. 2015). Data from the Nurse's Health Study demonstrated a dose response between non-users, less frequent users, and daily users. (Woolen 2022, Supp. Table 1). Similarly, the O'Brien (2024) publication looking at the Sister Study cohort found an even higher increased risk with frequent use and long duration of use. Modern medicine also recognizes that a monotonic dose-response curve is often overly simplistic (e.g., asbestos demonstrates a threshold rather a linear dose-response). Response can vary based on unique characteristics of the given population, exposure routes, molecular endpoints, individual susceptibility and synergistic or antagonistic effects of cumulative exposures. (Fedak et al. 2015). Given the limitations of the data, I consider this a less important factor when compared to the strength of the association, consistency, and the biological mechanism.

Plausibility

The general mechanism by which talcum powder products cause ovarian cancer is established as

an inflammation-induced process. It is well-accepted that particles reach the fallopian tubes and ovaries through migration/transport through the genital tract. These particles can also reach the pelvic organs through inhalation. The particles elicit an inflammatory tissue response and initiate a cascade of events and pathways at the cellular level that result in cancer formation. This process is well-described by the medical and scientific community. In addition, as previously discussed in this report, various components of talcum powder products, including asbestos and fibrous talc, are known carcinogens and known to cause cancer by similar mechanisms.

Coherence

The findings and conclusions from epidemiological, animal, and *in vitro* studies are coherent with what is known about ovarian cancer. There is also consistency with what is known about other gynecological malignancies and other cancers induced by environmental and occupational exposures.

Experiment

Causation of ovarian cancer by talcum powder is supported by laboratory (*in vitro* and *in vivo*) experiments. Research is ongoing which will further elucidate specific processes.

Prospective randomized controlled clinical trials to evaluate talcum powder products and their relationship to ovarian cancer are not feasible for a variety of ethical and methodological reasons. These include the recognized toxicity of talc, asbestos, and other constituents of talcum powder, the absence of therapeutic benefit, the long latency period, and the seriousness of ovarian cancer.

Analogy

As with consistency, plausibility, and coherence, the association between talcum powder and ovarian cancer is analogous to other diseases caused by various and specific carcinogens. For example, smoking causes lung cancer, asbestos causes mesothelioma and ovarian cancer, sun exposure causes skin cancer, and HPV causes cervical cancer. All of these cancers are the result of an inflammatory process initiated by a foreign agent.

Applying these Bradford-Hill guidelines and the principles of evidence-based medicine, it is my opinion that the genital use of talcum powder can cause ovarian cancer. In recent years, other scientists, physicians, and organizations have reached this same conclusion. (Health Canada 2021; IARC 2012; Penninkilampi and Eslick 2018; Schildkraut et al. 2016; Cramer et al. 2016).

Health Canada published its comprehensive final assessment on the health risks associated with talcum powder usage in the genital area, reaching similar conclusions described in my analysis. (Health Canada Assessment 2021). The human health portion of Health Canada's assessment underwent external peer review. These conclusions include:

1. “With regards to perineal exposure, analyses of the available human studies in the peer-reviewed literature indicate a consistent and statistically significant positive association between perineal exposure to talc and ovarian cancer.” (iii)
2. “The available data are indicative of a causal effect.” (iii)
3. “Although there are uncertainties related to bias [in the epidemiological studies], there is confidence in the robustness of the available database for use in characterizing cancer risk

attributed to talc exposure. Furthermore, the available data are indicative of a causal relationship.” (36)

4. Referencing at least 15 documents and articles, “[p]articles of talc are able to migrate into the pelvis and ovarian tissue...” (33)
5. “[T]here is support for an association on inflammation and increased risk of ovarian cancer.” (20-21)
6. “With respect to talc and induction of tumours, local chronic irritation leading to an inflammatory response is one possible mechanism of tumour progression that is frequently cited in the literature.” (20-21)

XI. SUMMARY OF GENERAL OPINIONS

The opinions in this report are provided to a reasonable degree of medical and scientific certainty. A summary of these opinions follows:

1. Based on epidemiological studies, the established biological mechanism, and evidence of the presence of asbestos, fibrous talc, and other known carcinogens, talcum powder products cause epithelial ovarian cancer in some women. The genital use of talcum powder products presents a significant risk factor for ovarian cancer for *all* women who use the products.
2. When looking at epidemiological studies in their totality, the data demonstrates a consistent, replicated, and statistically significant increased risk of developing epithelial ovarian cancer with perineal talcum powder use.
3. Asbestos and fibrous talc are known human carcinogens, including ovarian cancer (IARC 2012) and have been shown to be present in Johnson’s Baby Powder and Shower to Shower. In addition, other known constituents of talcum powder products (including nickel, chromium, and cobalt) are carcinogenic, and their presence likely contributes to the cancer-causing properties of talcum powder products.
4. The extensive number of fragrance chemicals added to the talcum powder products likely contributes to the inflammatory properties, toxicity, and carcinogenicity of these products.
5. The migration/transport of talcum powder and its constituents, to the upper genital tract (tubes and ovaries) is a key element in the mechanism by which talcum powder products cause ovarian cancer. The evidence supporting migration is robust and universally accepted by the gynecologic community. In addition to perineal application resulting in migration and transport of particles and fibers through the genital tract, inhalation of these particles is another recognized route of exposure.
6. Inflammation/oxidative stress is an early and essential step in the molecular process by which talcum powder products cause ovarian cancer.
7. Cornstarch is a safer alternative to talcum powder.
8. Talcum powder use is a preventable causative risk factor for EOC.

Based on my education, training, experience and expertise in ovarian and other gynecologic cancers, review of the totality of the evidence, analysis and weighing the data in the context of Bradford Hill and the principles of evidence-based medicine, it is my professional opinion to a reasonable degree of scientific and medical certainty that Johnson's Baby Powder and Shower to Shower products cause epithelial ovarian cancer in some women. The use of talcum powder products presents a significant risk factor for ovarian cancer in *all* women who use the products.

Exhibit A

CURRICULUM VITAE

Judith K Wolf, MD

PRESENT TITLE AND AFFILIATION

Gynecologic Oncologist
Locum Tenens
01/2021 to present

Goshen Center for Cancer Care, Goshen, IN 4/2020- 6/2022
Rochester General Hospital, Rochester NY 1/2021-12/2021
Hershey Medical Cancer, Hershey PA 4/2022-7/2023
Park Nicolett Minneapolis, MN 4/2023-10/2023

CITIZENSHIP

United States

PREVIOUS WORK EXPERIENCE

Gynecologic Oncologist
Community Health Network
Clearvista Parkway
Indianapolis, IN
06/2018 to 01/2021

Chief Medical Officer
ProvistaDx
55 Broad St 18th Floor
New York, NY 0004
6/2016-6/2018

Chief Medical Officer
Vermillion, Inc
12117 Bee Caves Rd
Austin TX 78738
9/2014-6/2016
9/2014- 6/2016

Division Chief of Surgery
Banner MD Anderson Cancer Center
2946 E Banner Gateway Dr
Gilbert, AZ 85235
6/2011-9/2014

Professor of Gynecologic Oncology
The University of Texas MD Anderson Cancer Center
1515 Holcombe Blvd
Houston, TX 77030
7/1995-6/2011

EDUCATION**Degree-Granting Education**

University of Akron, Akron, OH, BS, 1982, Natural Sciences

Northeastern Ohio Universities College of Medicine, Rootstown, OH, MD, 1986, Biomedical Science

The University of Texas Health Science Center at Houston, Houston, TX, MS, 1993, Biomedical Sciences- Thesis, Characterization of two populations of the human ovarian cancer cell line, 2774, that express different levels of epidermal growth factor receptor.

Postgraduate Training

Residency, Obstetrics and Gynecology

U.T. Health Science Center at San Antonio, San Antonio, TX, Dr. Carl J. Pauerstein

07/1986-06/1990

Fellowship, Gynecologic Surgery

University of Minnesota, Duluth, MN, Dr. Leo Twiggs

07/1990-6/1991

Fellow, Gynecologic Oncology, Department of Biology The University of Texas MD Anderson Cancer Center, Houston, TX, Dr. J Taylor

Wharton 07/91-06/93

Junior Faculty Associate, Gynecologic Oncology The University of Texas MD Anderson Cancer Center, Houston, TX, Dr. J. Taylor Wharton

07/1993-06/1995

CREDENTIALS**Board Certification**

American Board of Obstetrics and Gynecology, (Written Exam), 1990
American Board of Obstetrics and Gynecology: Special Qualification in Gynecologic Oncology, (Written Exam), 1996
American Board of Obstetrics and Gynecology, 1997
-Recertified 2022- 12/31/2023
American Board of Obstetrics and Gynecology: Special Qualification in Gynecologic Oncology, 2000
-Recertified 2022-12/31/2023

Licensures

Active

State of Arizona, AZ, 45110, 7/2011 – current
State of Indiana, IN 01074549B, 9/2014- current
State of Georgia, GA 173182 6/2014- present
State of Wisconsin 71734-20 9/5/2019-present
State of New York 307831 12/2020 to present
State of North Carolina 257141 2/13/2020 to present
State of Pennsylvania MD476656 1/31/2022 to present
State of Virginia 0101275018 4/27/2022 to present
State of Tennessee 66290 10/7/2022 to present
State of Minnesota 33916 1/1990-1/1993 and 4/18/23 to present

Inactive

State of Kentucky- temporary license TP 106 9/6/22-4/1/2023
State of Texas, TX, H4856, 1988-8/2012

EXPERIENCE/SERVICE

Academic Appointments

Assistant Professor, Department of Gynecologic Oncology, Division of Surgery, The University of Texas M.D. Anderson Cancer Center, Houston, TX, 1995-1999
Assistant Professor, Department of Gynecologic Oncology, Division of Surgery, The University of Texas M.D. Anderson Cancer Center, Houston, TX, 1999-2002
Associate Professor, Department of Gynecologic Oncology, Division of Surgery, The University of Texas M.D. Anderson Cancer Center, Houston, TX, 2002-8/2008
Graduate Faculty, Biomedical Sciences, Graduate School of Biomedical Sciences, The University of Texas Houston Health Science Center, Houston, TX, 2003-2011
Associate Professor, Department of Gynecologic Oncology, Blanton Davis Ovarian Cancer Research Program, The University of Texas M. D. Anderson Cancer Center, Houston, TX, 2006-8/2008
Associate Director, Department of Gynecologic Oncology, Developmental Therapeutics, The University of Texas MD Anderson Cancer Center, Houston, TX, 2006-2011
Co-Division Director, Department of Gynecologic Oncology, Division of Surgery, Baylor College of Medicine, Houston, TX, 4/2006-4/2007

Professor, Department of Gynecologic Oncology, Blanton Davis Ovarian Cancer Research Program, The University of Texas MD Anderson Cancer Center, Houston, TX, 2008-2011

Associate Director, Department of Gynecologic Oncology, Developmental Therapeutics, The University of Texas MD Anderson Cancer Center, Houston, TX, 2011

Division Chief, Surgical Oncology, Banner MD Anderson Cancer Center, Gilbert, AZ 6/2011-9/2014

Vice Chair, Department of Oncology Services, Banner MD Anderson Cancer Center, Gilbert, AZ 6/2011-9-2014

Adjunct Professor, Gynecologic Oncology, University of Texas, MD Anderson Cancer Center, Houston, Texas, 2012- 2014

Clinical Professor, Division of Clinical Education, Arizona College of Osteopathic Medicine, Midwestern University, Arizona, 2012- 2014

Administrative Appointments/Responsibilities

Assistant Program Director (Research), Fellowship in Gynecologic Oncology, Division of Surgery, The University of Texas M. D. Anderson Cancer Center, Houston, TX, 1999-2004

Medical Director, Community Relations, Department of Gynecologic Oncology, Division of Surgery, The University of Texas MD Anderson Cancer Center, Houston, TX, 4/2008-2011

Other Appointments/Responsibilities

Member, Felix Rutledge Society, Houston, TX, 1995-Present
President, Felix Rutledge Society, 2008-2009

Member, Society of Gynecologic Oncologists, Chicago, IL, 1996-Present

Member, Quality and Outcomes Committee, Society of Gynecologic Oncology, 2012-Present

Member, Breakthrough Series; Improving Care at the End of Life, Houston, TX, 1997-2011

Founder-Chairman, Sprint for Life 5K Fun Run, M. D. Anderson Cancer Center, Houston, TX, 1998-Present

Chairman, Medical and Scientific Advisory Board, National Ovarian Cancer Coalition, Dallas, TX, 2003-Present

President, Houston Gynecologic & Obstetrics Society, Houston, TX, 2003-2004

Treasurer, Houston Gynecologic & Obstetrics Society, Houston, TX, 1998-2000

Vice President, Houston Gynecologic & Obstetrics Society, Houston, TX, 2001-

Member, Gynecologic Oncology Group, Philadelphia, PA, 2001-2011

Departmental Liaison, M D Anderson Cancer Center Women Faculty Programs, Houston, TX, 2/2010-2011

Endowed Positions

N/A

Consultantships

N/A

Military or Other Governmental Service

N/A

Institutional Committee Activities

Medical Records Committee, Member, 1995–2011
Clinical Research Committee, Member, 1997–2000
Women's Faculty Administrative Organization Steering Committee, Member, 1998–1999
Cancer Committee, Hermann Hospital, Member, 1998–2001
Search Committee, Anesthesia, Member, 1999–2000
Ovarian SPORE Executive Committee, Member, 1999–2011
Student and Trainee Resources-Clinical Fellow's Research Award, Faculty Reviewer, 1999
Cancer Therapeutics Discovery Program Grants, Reviewer, 2000–2004
Clinical Research Committee, Member, 2001–2004
Search Committee, Internal Medicine, Member, 2001
Uterine SPORE Executive Committee, Member, 2003–2011
Faculty Promotion and Tenure Committee, Division of Surgery, Member, 2003–2011
Gynecologic Oncology Surgical Research Program (GO-SRP) Committee, Member, 2004–2011
Fellowship Planning Committee, Member, 2004–2011
Blanton-Davis Ovarian Cancer Research Program Executive Committee, Member, 2004–2011
Faculty Celebration Steering Committee, Member, 2004
Gynecologic Oncology Center for Surgical Research (GOCSR), Member, 2004
Ovarian Working Group, Department of Gynecologic Oncology, Chairman, 2005–2011
Search Committee, Department of Nephrology Chair, Member, 2005
Gynecologic Oncology T32 - Program Steering Committee, Member, 2005
The University of Texas M. D. Anderson Cancer Center, Gynecologic Oncology Group (GOG), Co-Principal Investigator, 2005–2011
Faculty Celebration Gala, Chairman, 2005
Faculty Leadership Committee, Member, 2006–2011
Executive Committee of Faculty Senate, Member, 2007–2009
Faculty Senate Committee, Chair Elect, 2010–2011
 Faculty Senate Committee, Chair, 2011 – 2012
 Faculty Senate Committee, Member, 2006–2011
Gynecologic Oncology Committee for New Institute of Personalized Cancer Therapy, Head, 4/2008–2011
Award Nomination Selection Committee, 2010–2011
Clinical Research Counsel, Member, 6/2008–2011
Clinical Research Committee, Member, 7/2009–2011
Women Faculty Programs, Member, 8/2009–2011
Charitable Activities Committee Subcommittee, Member, 2010–2011
OPPE/FPPE, Department Safety Officer, 2/2010–2011
Institutional Review Board 1 (IRB1), Associate Member, 8/2010–2011
Vice Chair, Department of Oncology Services, BMDACC, 2011- 2014
BMDACC Perioperative Logistic Committee, 2011- 2014
BMDACC Surgery Committee, 2011- 2014t
BMDACC Phase II Steering Committee, 2011-2014
Relationship Committee between UT MD Anderson Cancer Center and BMDACC, 2011- 2014
BMDACC Research Faculty Guidance Committee, 2011- 2014
Banner Medical Group Knowledge Management Committee, 2012- 2014
BMDACC, Affiliate of UTMDACC for Gynecologic Oncology Group (GOG), Principal Investigator, 2012- 2014
BMDACC Biospecimen Governance Committee Chair 2013- 2014
BMDACC Research Committee, Co-chair 03/2013- 2014
Banner Health Oncology Steering Committee, 5-9/2014

HONORS AND AWARDS

Medical Honor Society, Alpha Omega Alpha, 1986
Galloway Fellowship in Gynecologic Oncology, Memorial Sloan Kettering Cancer Center, 1989
Best Doctors in America®, 2005–2006, 2006–2007, 2007–2008, 2011, 2013

RESEARCH

Grants and Contracts (past 5 years)

Funded

Principal Investigator-MDACC, J. S. Blanton Research Fund, J. S. Blanton Research Fund, 1999–2011, \$116,367
Principal Investigator, 10%, Gene Developmental in Ovarian Cancer, Specialized Program of Research Excellence, 2001– 2011, \$50,000
Principal Investigator, Gene Therapy Development Award, W. M. Keck Center for Cancer Gene Therapy Development Award, 2001– 2011, \$50,000
Principal Investigator, Texas Federation of Business Professional Women Award, Texas Federation of Business Professional Women Award, 2001– 2011, \$6,337
Principal Investigator, The Ovarian Cancer Survivors Fund, Don-Ray George & Associates, 2003 – 2011, \$116,126
Co-Investigator, Efficacy and Mechanism of SERMs for Recurrent / Advanced Endometrial Cancer, Molecular Progression of Endometrial Cancer, P150CA098258, Specialized Program of Research Excellence, PI - Karen H. Lu, 9/1/2003 – 8/31/2008, \$992,019

Principal Investigator-MDACC, Gynecologic Oncology Center for Surgical Research (GOCSR), Houston Jewish Community Foundation, 2004 – 2011, \$50,000

Principal Investigator-MDACC, Susan G. Koch Ovarian Cancer Research Fund, Susan G. Koch, 2005 – 2011, \$50,000

Co-Investigator, The University of Texas M D Anderson Cancer Center, Gynecologic Oncology Group, Gynecologic Oncology Group, PI - Robert Coleman, M.D., 2005 – 2011.

Pending

N/A

Other

N/A

Completed

Principal Investigator, Evaluation of the Effect and Mechanism of Action of Adenovirus-mediated Tumor Suppressor Gene Therapy of Ovarian Cancer, Gynecologic Cancer Foundation, 1998–2006, \$25,000

Co-Investigator, Evaluating Fatigue and Other Symptoms of Ovarian cancer Patients with Ecological Momentary Assessment, Ovarian Cancer Research Development Award, PI - Karen Basen Engquist, Ph.D., 1999–2006, \$50,000

Not Funded

N/A

Protocols

Funded

Principal Investigator, Evaluating Fatigue and Other Symptoms of Ovarian Cancer Patients with Ecological Momentary Assessment, ID99-, 1999, Ovarian Cancer Research Development Award

Principal Investigator, A Phase II Study of Oral Xeloda Administered Twice Daily for Fourteen Days Every Three Weeks to Patients with Advanced Ovarian, Tubal or Peritoneal Cancer Refractory to Platinum and Taxanes, GYN 00-275, 2000–2001

Co-Principal Investigator, Phase II Evaluation of Oxaliplatin In Persistent or Recurrent Squamous Cell Carcinoma of the Cervix, GOG127P, PI - Charles Levenback, 2000–2003, GOG

Principal Investigator, A Phase 1 Dose Escalation Study of Intraperitoneal E1A Lipid Complex (1:3) with Combination Chemotherapy in Women with Epithelial Ovarian Cancer, ID 99-316, 2000–2006

Co-Principal Investigator, A Phase II Evaluation of Thalidomide (NSC #66847, IND #48832) In the Treatment of recurrent or Persistent Leiomyosarcoma of the Uterus, GOG231B, PI - Diane Bodurka, 2001–2002, GOG

Co-Principal Investigator, A Phase II Multicenter Study of Oral Xeloda Administered Twice Daily for Fourteen Days Every Three Weeks to Patients with Advanced or Recurrent Cervical Cancer, GYN01-080, PI - Lois Ramondetta, M.D., 2001–2003

Collaborator, A 2-Part Phase I/II Study of Extended Field External Irradiation and Intracavitary Brachytherapy combined with Chemo (Weekly Cisplatin-Arm 1) and Amifostine (Weekly Cisplatin and Amifostine-Arm 2), RTOG-C0116, PI - Anuja Jhingran, M.D., 2001– 2011, RTOG

Principal Investigator, A Phase I/II Study to Evaluate the Maximum Biologic Dose of Pegylated-Interferon (PEG- INTRO) in Patients with Platinum Resistant Ovarian, Peritoneal, or Fallopian Tube Cancer, ID02-115, 2002–2005, \$100,000, Integrated Therapeutics Group/Schering Plough

Collaborator, A Phase II Evaluation of Decetaxel and Gemcitabine Plus G-CSF in the treatment of recurrent of Persistent Leiomyosarcoma of the Uterus, GOG-0131G, PI - Lois Ramondetta, M.D., 2002–2005, GOG

Collaborator, A Phase II Evaluation of Liposomal Doxorubicin (Doxil) in the Treatment of Persistent or Recurrent Squamous Cell Carcinoma of the Cervix, GOG 127-R, PI - Diane Bodurka, M.D., 2002–2005, GOG

Co-Principal Investigator, Phase II Study of Irofulven (IND #48914) in Patients with Refractory or Recurrent Advanced Epithelial Ovarian Cancer Using Every-Other-Week Dosing, GYN01-486, PI - Diane Bodurka, 2002–2005

Collaborator, A Phase II Evaluation of Capecitabine (NSC#712807) in the Treatment of Persistent or Recurrent Non-squamous Cell Carcinoma of the Cervix, GOG-0128G, PI - Diane Bodurka, M.D., 2002– 2011, GOG

Collaborator, Treatment of Patients with Stage IB2 Carcinoma of the Cervix: A Randomized Comparison of Radical Hysterectomy and Tailored Chemo-Radiation versus Chemo-radiation, GOG0201, PI - Charles Levenback, M.D., 2003–2005, GOG

Collaborator, A Randomized Study of Tamoxifen versus Thalidomide (NSC no.66847) in Patients with Biochemical-Recurrence- Only Epithelial Ovarian Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma after First-Line Chemotherapy, GOG-0198, PI - Robert Coleman, M.D., 2003–2006, GOG

Collaborator, A Phase I/II Study of COX-2 Inhibitor, Celebrex (Celecoxib), and Chemoradiation in Patients with Locally Advanced Cervical Cancer, RTOG-C0128, PI - Patricia Eifel, M.D., 2003–2011, RTOG

Principal Investigator, A Phase I/II Study of Gleevec/Taxol in Patients with Newly Diagnosed Stage IIIC or IV or Recurrent (any stage) Uterine Papillary Serous Carcinoma (UPSC), GYN03-0177, 2003–2011, Novartis

Collaborator, A Phase III Clinical Trial of Tisseele VH Fibrin Sealant to Reduce Lymphedema Incidence after Inguinal Lymph Node Dissection Performed in the Management of Vulvar Malignancies, GOG195, PI - Pedro Ramirez, M.D., 2003–2011, GOG

Collaborator, A Phase III Randomized Clinic Trial of Laparoscopic Pelvic & Para-Aortic Node Sampling with Vaginal Hysterectomy and BSO versus Open Laparotomy with Pelvic and Para-Aortic Node Sampling and Abdominal Hysterectomy and BSO in Endometrial Adenocarcinoma and Uterine Sarcoma, GOG-LAP2, PI - Pedro Ramirez, M.D., 2003–2011, GOG

Collaborator, A Phase III Randomized Trial of Paclitaxel and Carboplatin versus Triplet or Sequential Doublet Combinations in Patients with Epithelial Ovarian or Primary Peritoneal Cancer, GOG-0182, PI - John Kavanagh, M.D., 2003–2011, GOG

Collaborator, A Randomized Phase III Study of Paclitaxel plus Cisplatin versus Vinorelbine Plus Cisplatin versus Gemcitabine Plus Cisplatin versus Topotecan Plus Cisplatin in Stage IVB, Recurrent or Persistent Carcinoma of the Cervix, GOG-0204, PI - Charles Levenback, M.D., 2003–2011, GOG

Principal Investigator, Phase I/II Study of Weekly Topotecan and Iressa in Patients with Platinum-Resistant Ovarian/Peritoneal/Fallopian Tube Cancer, 2003-0322, 2004–2007, \$92,500, GlaxoSmithKline/Astra Zeneca

Principal Investigator, A Phase I/II Randomized Study of Intraperitoneal tgDCC-E1A and Intravenous Paclitaxel in Women with Platinum-Resistant Ovarian Cancer, ID02-321, 2004–2011, \$365,000, Marcus Foundation Funds-UT M. D. Anderson Cancer Center

Principal Investigator, A Phase II Study of RAD001 in Patients with Recurrent Endometrial Cancer, 2004-0002 IND 69277, 2004–2011, \$111,300, Novartis

Collaborator, A Randomized, Phase II Trial of Doxorubicin/Cisplatin/Paclitaxel and G-CSF versus Carboplatin/Paclitaxel in Patients with Stage III and IV or Recurrent Endometrial Cancer, GOG-0209, PI - Lois Ramondetta, M.D., 2004–2011, GOG

Mentor, Training Grant - Department of Gynecologic Oncology, Training of Academic Gynecologic Oncologists, NIH/NCI, 1 T32CA101642-01A, PI - David M. Gershenson, MD, 2005–2010, \$1,535,549 (\$181,757/year), NIH/NCI

Collaborator, A Limited Access Phase II Trial of Cetuximab (C225, NSC 714692) in Combination with Cisplatin (NSC #119875) in the Treatment of Advanced, Persistent, or Recurrent Carcinoma of the Cervix, GOG-0076DD, PI - Robert Coleman, M.D., 2005–2011, GOG

Principal Investigator, A Phase I Trial of Tailored Radiation Therapy with Concomitant Cetuximab (C225, NSC# 714692) and Cisplatin (NSC# 119875) in the Treatment of Patients with Cervical Cancer, GOG-9918, 2005–2011, GOG

Collaborator, A Phase II Evaluation of Pemetrexed (Alimta, LY231514, IND #40061) in the Treatment of Recurrent Carcinoma of the Cervix, GOG-0127T, PI - Charles Levenback, M.D., 2005–2011, GOG

Collaborator, A Phase II Evaluation of Thalidomide (NSC# 66847, IND# 48832) In The Treatment Of Recurrent Or Persistent Carcinosarcoma of the Uterus, GOG-0230B, PI - Lois Ramondetta, M.D., 2006–2007, GOG

Principal Investigator, A Dose-Escalating Phase I Study with an Expanded Cohort to Assess Feasibility of Intraperitoneal Carboplatin & Intravenous Paclitaxel in Patients with Previously Untreated Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancer, GOG-9917, 2006–2011, GOG

Collaborator, A Phase II Evaluation of Pemetrexed (Alimta, LY231514, IND #40061) in the Treatment of Recurrent or Persistent Platinum-Resistant Ovarian or Primary Peritoneal Carcinoma, GOG-0126Q, PI - Siqing Fu, M.D., 2006–2011, GOG

Co-Principal Investigator, A Phase II Study of Faslodex in Recurrent/Metastatic Endometrial Carcinoma, GOG-0188, PI - Lois Ramondetta, M.D., 2006–2011, GOG

Co-Principal Investigator, Phase III Carboplatin & Paclitaxel + Placebo vs. Carboplatin & Paclitaxel + Concurrent Bevacizumab (NSC #704865, IND # 7921) follow by Placebo, vs Carboplatin & Paclitaxel + Concurrent & Ext Bevacizumab, in Advanced Stage Epithelial Ovarian & Peritoneal Primary Cancer, GOG-0218, PI - Robert Coleman, M.D., 2006–2011, GOG

Collaborator, A Phase II Evaluation of ABI-007 (IND #55,974) in the Treatment of Persistent or Recurrent Squamous or Non Squamous Cell Carcinoma of the Cervix (Abraxis BioScience, Inc. Study #CA026) (Group B), GOG-0127V, PI - Robert Coleman, M.D., 2007–2011, GOG

Principal Investigator, Preliminary Evaluation of Femara (Letrozole) for Adjuvant Treatment After Completion of First-Line Chemotherapy for Patients with Optimally Debulked and Chemoresponsive Ovarian Cancer, IRB 2006-0689, 2007–2011, \$314,989

Principal Investigator, Randomized Phase 2 Study of MLN8237, an Aurora A Kinase Inhibitor, Plus Weekly Paclitaxel or Weekly Paclitaxel Alone in Patients with Recurrent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Preceded by a Phase 1 Portion in Patients with Ovarian or Breast Cancer, Millennium.

Unfunded

Collaborator, A Phase II Study of Intravenously Administered Tirapazamine Plus Cisplatin in Subjects with Cervical Cancer, GYN96-136, PI - Charles Levenback, M.D., 1996–2004

Principal Investigator, Phase I Study of recurrent ovarian cancer Adp53, ID 97-288, 1997

Collaborator, Telomerase Testing in Peritoneal Washings from Ovarian Cancer Patients Undergoing Second Look Laparotomy, LAB98-080, PI - David Gershenson, M.D., 1998–2005

Collaborator, A Pilot Study of Transfusion of rhTPO-Derived Autologous Platelets Cryopreserved with Thromobosol and 2% DMSO in Patients with Gynecologic Malignancy Receiving Carboplatin, GYN97-310, PI - Saroj Vadhan, 1999–2004

Collaborator, Paclitaxel, Carboplatin, and Herceptin for Patients with Untreated Advanced, (Cohort A) or Recurrent Platinum-Sensitive (Cohort B) Epithelial Ovarian Cancer, Peritoneal Cancer, or Fallopian Tube Cancer, GYN99-067, PI - David Gershenson, M.D., 1999–2004

Collaborator, Paclitaxel, Carboplatin, and Herceptin for Patients with Untreated Advanced Epithelial Ovarian Cancer, Peritoneal Cancer, or Fallopian Tube Cancer, GYN99-132, PI - David Gershenson, M.D., 1999–2007

Collaborator, Feasibility of Measuring Gene Expression Patterns Using Tissue Acquisition of Primary Stage III and IV Epithelial Ovarian Cancer, Fallopian Tube, or Primary Peritoneal Cancer and Gene Expression Array Technology for Predicting Paclitaxel Chemotherapy Sensitivity and Resistance, ID00-408, PI - David Gershenson, M.D., 2000–2011

Principal Investigator, Phase II Study of Paclitaxel for Ovarian Stromal Tumors as First-Line or Second-Line Therapy, GOG-0187, 2000

Collaborator, A Phase II Study of Intraperitoneal E1A-Lipid complex for Patients with Advanced Epithelial Ovarian CX without Her-2/Neu Overexpression, ID00-306, PI - Naoto Ueno, 2001–2002

Collaborator, Phase II Study of Intraperitoneal Recombinant Human Interleukin-12 (RHIL-12) in Patients with Peritoneal Carcinomatosis (Residual Disease <1cm) Associated with Ovarian epithelial CX or Primary Peritoneal Carcinoma, ID00-232, PI - Renato Lenzi, 2001–2005

Collaborator, Feasibility Study of Intraoperative Lymphatic Mapping and Sentinel Lymph Node Identification in Patients with Endometrial Cancer, ID01-290, PI - Diane Bodurka, M.D., 2001–2006

Collaborator, A Phase II Multicenter Trial of Paclitaxel and Carboplatin in Women with Advanced (IIlb, IIIC, IVa and IVb) or Recurrent (All Stages) Mixed Malignant Mullerian Tumors (MMMT) of the Uterus, ID01-229, PI - Lois Ramondetta, M.D., 2001–2011

Collaborator, A Phase II Study: Paclitaxel and Pelvic Radiation for Stage I-IIIA Papillary Serous Carcinoma of the Endometrium, ID-418, PI - Anuja Jhingran, 2001–2011

Collaborator, Chemotherapy-Related Toxicities in Ovarian Cancer Patients: Preference Assessments of Patients, Family Members, Ancillary Staff and Gynecologic Oncologists, and Patients' Quality of Life, GYN00-409, PI - Diane Bodurka, M.D., 2001–2011

Collaborator, Clinical and Molecular Genetic Determinants of Late Complication in Patients Treated with Radiation Therapy for Cervical Cancer, LAB01-380, PI - Patricia Eifel, M.D., 2001–2011

Collaborator, Evaluating Fatigue and Other Symptoms of Ovarian Cancer Patients with Ecological Momentary Assessment, ID00-013, PI - Karen Basen-Engquist, 2001–2011

Collaborator, Phase II Study of Mifepristone (RU-486) in the Treatment of PR Positive Advanced/Recurrent Endometrial Adenocarcinoma and Low Grade Endometrial Stromal Sarcoma (LGESS), ID01-212, PI - Lois Ramondetta, M.D., 2001–2011

Collaborator, Use of the CA125 Algorithm for the Early Detection of Ovarian Cancer in Low Risk Women, ID01-022, PI - Karen Lu, 2001–2011

Co-Principal Investigator, Vacuum-Assisted Closure in the treatment of Gynecologic Oncology Wound Failures, RCR01-156, PI - Pedro Ramirez, 2002–2003

Collaborator, Phase I Trial of Concurrent Weekly CPT-11, Cisplatin, and Radiotherapy for Patients with Newly Diagnosed Stage IIIB-IVa Cancer of the Uterine Cervix, ID02-526, PI - Pedro Ramirez, M.D., 2002–2005

Collaborator, A Phase II Study of Chemoimmunotherapy for Patients with Potentially Platinum Sensitive Müllerian (Epithelial Ovarian, Peritoneal, or Fallopian Tube) Carcinomas, ID02-231, PI - Ralph Freedman, M.D., Ph.D., 2002–2011

Collaborator, A Prevalence Study of HNPCC Gene Mutation in Women with Endometrial Cancers, ID01-533, PI - Karen Lu, M.D., 2002–2011

Collaborator, Feasibility of Measuring Gene Expression Patterns Using Tissue Acquisition of Primary Peritoneal CX and Gene Expression Array Technology for Predicting Paclitaxel Chemo Sensitive and Resistant, ID00-408, PI - David M. Gershenson, M.D., 2002–2011

Collaborator, Modulation of Putative Surrogate Endpoint Biomarkers in Endometrial Biopsies from Women with HNPCC, ID01-340, PI - Karen Lu, M.D., 2002–2011

Collaborator, The Utility and Impact of Computed Tomography and Serum CA-125 in the Management of Newly Diagnosed Ovarian Cancer, ID02-143, PI - Pedro Ramirez, M.D., 2002–2011

Co-Principal Investigator, Evaluation of Molecular Markers in Malignant Mixed Mesodermal Tumors (MMMT) of the Ovary, LAB03-0653, PI - Lois Ramondetta, M.D., 2003-2005
Co-Principal Investigator, A Phase I Study Evaluating the Safety and Tolerability of PS-341(Bortezomib) and Carboplatin in Patients with Platinum Resistant Recurrent Ovarian Cancer, Primary Peritoneal Cancer, and Fallopian Tube Cancer, ID02-114, PI - Pedro Ramirez, 2003-2007
Collaborator, Phase III Randomized Study of TLK286 Versus Doxil/Caelix or Hycamtin as Third-Line Therapy in Platinum Refractory or Resistant Ovarian Cancer, ID03-184, PI - John Kavanagh, M.D., 2003-2007
Co-Principal Investigator, Role of Secondary Cytoreductive Surgery for Recurrent Ovarian: A 20-Year Experience, RCR03-0803, PI - Pedro Ramirez, 2003-2007
Collaborator, A Phase II Study Evaluating the Utility of Letrozole in the Treatment of Recurrent, Estrogen Receptor (ER) Positive, Epithelial Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer, ID02-698, PI - Pedro Ramirez, M.D., 2003-2011
Collaborator, A Pilot Study of Laparoscopic Extraperitoneal Lymph Node Dissection in Patients with Locally Advanced Cervical Cancer, ID03-0098, PI - Pedro Ramirez, M.D., 2003-2011
Collaborator, Phase 1-2a Dose-Ranging Study of TLK286 in Combination with Doxil in Platinum Refractory or Resistant Ovarian Cancer, ID02-571, PI - John Kavanagh, M.D., 2003-2011
Collaborator, Phase II Study of Letrozole in Patients with Recurrent Advanced Borderline Tumors or Low Grade Epithelial Cancers of the Ovary, Fallopian Tube and Primary Peritoneum, 2003-0486, PI - John Kavanagh, M.D., 2003-2011
Collaborator, Quality of Life and Preferences of Ovarian Cancer Patients Enrolled on a Randomized Trial of High-Dose versus Conventional Dose Chemotherapy, ID02-680, PI - Charlotte Sun, Ph.D., 2003-2011
Co-Principal Investigator, A Phase II Study of Gemcitabine and Cisplatin for Advanced or Recurrent Endometrial Cancer, 2003-0823, PI - Jubilee Brown, M. D., 2004-2011
Collaborator, Chemoradiation-Induced Nausea and Emesis: A Prospective Study to Assess Patient Preferences and Quality of Life, 200-0529, PI - Charlotte Sun, Ph.D., 2004-2011
Collaborator, The Role of Appendectomy at the Time of Tumor Reductive Surgery in Patients with Epithelial Ovarian Cancer, RCR05-0630, PI - Pedro Ramirez, M.D., 2005
Collaborator, Total Laparoscopic Radical Hysterectomy: Outcomes Evaluation, RCR05-0390, PI - Pedro Ramirez, M.D., 2005-2007
Co-Principal Investigator, A Pilot Clinical Trial with Molecular Marker Study of Chemosensitization to Carboplatin by Use of Vidaza in Platinum Resistant or Refractory Epithelial Ovarian Cancer, 2005-0009, PI - Siqing Fu, M.D., 2005-2011
Collaborator, Evaluation of Demographics and Perioperative Care of Patients Undergoing Laparoscopic Surgery for Gynecologic Malignancies: A 15-Year Experience, RCR05-0137, PI - Pedro Ramirez, M.D., 2005-2011
Collaborator, Systemic Antineoplastic Therapy in Ovarian Cancer Patients with Renal Dysfunction, RCR05-0707, PI - John Kavanagh, M.D., 2005-2011
Collaborator, A Phase I Dose Escalation Study of ABI-007 with Carboplatin as First-Line Therapy in Patients with Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma, 2006-0405, PI - Robert Coleman, M.D., 2006-2011
Principal Investigator, Phase II Study of Cetuximab (Erbitux) in Patients with Progressive or recurrent Endometrial Cancer, 2006-0211, 2006-2011
Collaborator, A Multi-Institutional Study of Proteomic Evaluation of Epithelial Ovarian Cancer, Primary Peritoneal Cancer, and Fallopian Tube Cancer Patients in First Clinical Remission: Development of a Protein Fingerprint Profile of Relapse, 2005-0780, PI - Karen Lu, M.D., 2007-2011
Co-Principal Investigator, A Phase II, Open-Label, Non-Comparative, International, MC Study to Assess the Efficacy and Safety of KU-0059436 Given Orally Twice Daily in Patients with Advanced BRCA1-or BRCA2-Associated Ovarian Cancer, 2007-0098, PI - Karen H. Lu, M.D., 2007-2011
Collaborator, A Study of the Efficacy of MORAb-003 in Subjects with Platinum-Sensitive Epithelial Ovarian Cancer in First Relapse, 2006-0889, PI - Robert Coleman, M.D., 2007-2011
Collaborator, Phase I/II and Pharmacokinetic Study of Docetaxel Plus VEGF Trap (AVE0005, NSC #724770) In Patients with Recurrent Ovarian, Primary Peritoneal, and Fallopian Tube Cancer, 2006-0329, PI - Robert Coleman, M.D., 2007-2011

Patents and Technology Licenses

Patents

N/A

Technology Licenses

N/A

Grant Reviewer/Service on Study Sections

Review Committee on NIH CTRC, NIH, Member, Louisiana State University, 1997
AD HOC on NCI P01, NCI, Ad Hoc Member, Tulane University Health Science Center, 2004
Clinical Research Review Committee NCI, NCI, Member, Mayo Clinic, 2004
NIH-CONC Clinical Oncology Study Section Review (R01, R21), NIH, Member, Clinical Oncology Study Section Review (R01, R21), San Francisco, CA, 2004
Review Committee NCI-NIH, NIH, Member, Duke Comprehensive Cancer Center, Duke University, 2004
Review Committee on NCI-I Career Awards, NCI, Member, 2004
NCI P01 Cluster Review, NIH, Member, Bethesda, MD, 2005
NIH-CONC Clinical Oncology Study Section Review (R01, R21), NIH, Member, Clinical Oncology Study Section Review (R01, R21), Bethesda, MD, 2005
Review Committee NCI-NIH, PO1 Experimental Therapeutics II Cluster Review, NIH, Member, PO1 Experimental Therapeutics II Cluster Review, Rockville, MD, 2005

PUBLICATIONS

Peer-Reviewed Original Research Articles

1. Yu D, **Wolf JK**, Scanlon M, Price JE, Hung MC. Enhanced c-erbB-2/neu expression in human ovarian cancer cells correlates with more severe malignancy that can be suppressed by E1A. *Cancer Res* 1993 Feb 15;53(4):891-8.
2. Hamada K, Zhang WW, Alemany R, Roth JA, **Wolf JK**, Mitchell MF. Gene therapy of cervical cancer by adenovirus-mediated p53 gene transfer. *J Cell Biochem Suppl* 1995; 21A:421.
3. Gershenson DM, Morris M, Burke TW, Levenback C, **Wolf JK**, Warner D, Matthews CM, Wharton JT. Treatment of poor-prognosis sex cord-stromal tumors of the ovary with the combination of bleomycin, etoposide, and cisplatin(BEP). *Obstet Gynecol* 1996 Apr;87(4):527-31.

4. **Wolf JK**, Levenback C, Malpica A, Morris M, Burke T, Mitchell MF. Adenocarcinoma in situ of the cervix: significance of cone biopsy margins. *Obstet Gynecol* 1996 Jul; 88(1)(1):82-6.
5. Levenback C, Morris M, Burke TW, Gershenson DM, **Wolf JK**, Wharton JT. Groin dissection practices among gynecologic oncologists treating early vulvar cancer. *Gynecol Oncol* 1996 Jul; 62(1)(1):73-7.
6. Hamada K, Zhang WW, Alemany R, **Wolf JK**, Roth JA, Mitchell MF. Growth inhibition of human cervical cancer cells with recombinant adenovirus p53 in vitro. *Gynecol Oncol* 1996;60(3):373-379.
7. Mitchell MF, Hamada K, Jagannadha S, Satterfield WC, Buchholz S, **Wolf JK**, Zhang WU, Alemany R, Tortolero-Luna G, Keeling ME, Wharton JT, Roth JR. Transgene expression in the rhesus cervix mediated by an adenovirus expressing b-galactosidase. *Am J Obstet Gynecol* 1996;174:1094-1101.
8. Brader KR, **Wolf JK**, Hung MC, Yu D, Crispens MA, van Golen KL, Price JE. Adenovirus E1A expression enhances the sensitivity of an ovarian cancer cell line to multiple cytotoxic agents through an apoptotic mechanism. *Clin Cancer Res* 1997 Nov; 3(11):2017-24.
9. Gershenson DM, Silva EG, Levy L, Burke TW, **Wolf JK**, Tornos C. Ovarian serous borderline tumors with invasive peritoneal implants. *Cancer* 1998 Mar; 82(6)(6):1096-103.
10. Brader KR, **Wolf JK**, Chakrabarty S, Price JE. Epidermal growth factor receptor (EGFR) antisense transfection reduces the expression of EGFR and suppresses the malignant phenotype of a human ovarian cancer cell line. *Oncol Rep* 1998 Sep-Oct; 5(5):1269-74.
11. Price JE, **Wolf JK**, Pathak S. Distinctive karyotypes and growth patterns in nude mice reveal cross-contamination in an established human cancer cell line. *Oncol Rep* 1998 Jan-Feb; 5(1)(1):261-6.
12. **Wolf JK**, Kim TE, Fightmaster D, Bodurka D, Gershenson DM, Mills G, Wharton JT. Growth suppression of human ovarian cancer cell lines by the introduction of a p16 gene via a recombinant adenovirus. *Gynecol Oncol* 1999 Apr; 73(1)(1):27-34.
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Invited Articles

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Other Articles

1. **Wolf JK**. Gynecologic Cancer Treatment Update (Highlights from ASCO 2003). *Vital Signs Monograph*, Fall, 2003.
2. Herzog, Coleman R, McGuire, Monk B, Spriggs D, **Wolf JK**. Patterns of Practice in Selected Gynecologic Malignancies. *Colloquium at the Annual Meeting on Women's Cancer 2005* 36th Annual Meeting of the Society of Gynecologic Oncologists. (SGO Monograph), 2005.

Book Chapters

1. Hallum AV, III, Coleman RL, **Wolf JK**. Gynecologic Oncology. In: The M. D. Anderson Surgical Oncology Handbook. Ed(s) David H. Berger, Barry W. Feig, and George M. Fuhrman. Little Brown and Company: Boston, MA, 326-368, 1995.
2. Bevers MW, Bodurka Bevers DC, **Wolf JK**. Gynecologic Cancers. In: The M. D. Anderson Surgical Oncology Handbook, Second Edition. Ed(s) Barry W. Feig, David H Berger, and George M. Fuhrman. Lippincott Williams & Wilkins: Philadelphia, 377-424, 1998.
3. **Wolf JK**, Mills GB, Bast RC, et al. P53-mediated Gene Therapy. In: *Ovarian Cancer*. Ed(s) Frank Shart, Tony Blackett, Jonathan Berek and Robert Bast. Isis Medical Media Ltd: Oxford England, 259-27, 1998.
4. **Wolf JK**, Burke TW. Vulva/Vaginal Cancer. In: *Practical Strategies in Obstetrics and Gynecology*. Ed(s) Mitchell P. Dombrowski, S. Gene McNeely, Kamran S. Moghissi, and Adrian R. Munkarah. W. B. Saunders Company: Philadelphia, 449-457, 2000.
5. **Wolf JK**. Molecular Biology. In: *ACS Atlas of Clinical Oncology: Cancer of the Female Lower Genital Tract*. Ed(s) Eifel PJ, Levenback C. B.C. Decker, Inc: Hamilton London, 2001.
6. Bevers MW, Bodurka Bevers DC, **Wolf JK**. Gynecologic Cancers. In: The M. D. Anderson Surgical Oncology Handbook, Third Edition. Ed(s) Barry W. Feig, David H. Berger, and George M. Fuhrman. Lippincott Williams & Wilkins: Philadelphia, PA, 445-490, 2003.
7. Tanyi JL, Crotzer D, **Wolf JK**, Yu S, Hasegawa Y, Lahad J, Wa Cheng K, Umez-Goto M, Prestwich GD, Morris A, Newman RA, Felix EA, Lapis R, Mills GB. Lysophosphatidic Acid as a Targets for the Molecular Diagnosis and Therapy of Ovarian Cancer. A Review Article. In: *Functional Lipidomics*. Ed(s) Feng L, Prestwich GD. CRC Press Taylor & Francis Group: Boca Raton, FL, 101-123, 2005.

8. **Wolf JK**, Wharton JT. Surgery for Ovarian Cancer. In: Gynecologic Cancer. Ed(s) Gershenson DM, Eifel PJ, Kavanagh JJ, and Silva E. Springer-Verlag: New York, NY, 174-186, 2005.
9. Slomovitz BM, Soliman PT, **Wolf JK**. Gynecologic Cancers. In: The M. D. Anderson Surgical Oncology Handbook, Fourth Edition. Ed(s) Barry W. Feig, David H. Berger, and George M. Fuhrman. Lippencott Williams & Wilkins: Philadelphia, PA, 520-563, 2006.
10. Smith JA, **Wolf JK**. Ovarian Cancer. In: Pharmacotherapy: A Pathophysiologic Approach 8th Edition, 8th. Ed(s) DiPiro JT, Matzke GR, Yee GC, Talbert RL, Wells BG, Posey LM. McGraw-Hill Companies: Illinois. 2010.

Letters to the Editor

N/A

Manuals, Teaching Aids, Other Teaching Publications

N/A

Other Publications

N/A

EDITORIAL AND REVIEW ACTIVITIES

Editor/Service on Editorial Board(s)

N/A

Member of Editorial Review Board

Editorial Board Member, Clinical Ovarian Cancer: & Other Gynecologic Malignancies, CIG Media, 2008-present

Editorial Board Reviewer, European Journal of Clinical and Medical Oncology, San Lucas Medical Limited c/o Barefoot Investment Ltd,

Editorial Board of the Peer Reviewed Journal, 2010-present

Editorial Board Reviewer, American Society of Clinical Oncology, 2013 ASCO Educational Book

Editorial Advisory Board Reviewer, ADC Review/Journal of Antibody-drug Conjugates, 2013

Journal Reviewer

Reviewer, Gynecologic Oncology, 1995-present

Adhoc Reviewer, Obstetrics and Gynecology, 1996-present

Adhoc Reviewer, Clinical Cancer Research, 1998-present

Adhoc Reviewer, International Journal of Gynecologic Cancer, 1998-present

Adhoc Reviewer, International Journal of Radium Oncology, 1998-present

Adhoc Reviewer, Journal of Clinical Oncology, 1999-present

Adhoc Reviewer, American Journal of Pathology, 2001-present

Adhoc Reviewer, American Journal of Obstetrics and Gynecology, 2005-present

Other Editorial and Review Activities

Editor, Help Break the Silence.Talk about Ovarian Cancer, National Ovarian Cancer Coalition - NOCC Editors Event; New York, NY, April 29, 2008

TEACHING

Teaching Within Current Institution – Banner MD Anderson Cancer Center

Formal Teaching

Courses Taught

N/A

Training Programs

N/A

Other Formal Teaching

Lecturer, 1995-1999, Gynecologic Oncology for Enterostomal Therapy Nurses / Role of Gynecologic Oncologist talk given twice a year
1995-1999

Lecturer, 1998, Advances in Research for Ovarian Cancer / Sprint for Life Symposium
1998

Lecturer, 1998, Ovarian Cancer Treatment: Molecular Approaches / Grand Rounds
1998

Lecturer, 1999, Advances and Innovations in Ovarian Cancer / Sprint for Life Symposium
1999

Supervisory Teaching

Committees

Advisory Committees

Thesis Advisory Committee, GSBS, Christine Lee, MD, 2001-2003

Thesis Advisory Committee, GSBS, David Crotzer, MD, 2002-2004

Thesis Advisory Committee, GSBS, Monique Nillson, 2003-2005

Supervisory Committees

Chair, Thesis Supervisory Committee, GSBS, David Crotzer, MD, 2002-2004

Examining Committees

N/A

Direct Supervision

Undergraduate and Allied Health Students

N/A

Medical Students

4th Year Medical Students- Midwestern University, Phoenix, AZ

Graduate Students

GSBS, David Crotzer, MD, 2002-2004

Postdoctoral Research Fellows

Tae-Eu Kim Koreai, 1996-1997

Basic Science, Lois Ramondetta, MD, 1998

Basic Science, Pedro Ramirez, MD, 1998
Basic Science, Susan Modesitt, MD, 1999
Basic Science, Veronica Schimp, DO, 2000
Basic Science, Janos Tanyi, 2001–2004
Basic Science, Dwayne Jenkins, MD, 2001
Basic Science, David Crotzer, MD, 2002–2004

Clinical Residents and Fellows

Diljeet Singh, 7/1996–6/1999
Kenny Bozorgi, 7/1996–6/1999
Terri Pustilnik, 7/1996–6/1999
Lois M. Ramondetta, 7/1997–6/2000
Lynn P. Parker, 7/1997–6/2000
Mary E. Gordinier, 7/1997–6/2000
Carlos Herrera, 7/1998–6/2001
Lloyd West, 7/1998–6/2001
Pedro T. Ramirez, 7/1998–6/2001
Jubilee Brown Robinson, 7/1999–6/2002
Matthew Anderson, 7/1999–6/2002
Susan Modesitt, 7/1999–6/2002
Hyun Shvartsman, 7/2000–6/2003
Sean Tedjerati, 7/2000–6/2003
Veronica Schimp, 7/2000–6/2003
Alfred Dwayne Jenkins, 7/2001–6/2004
Amir Jazaeri, 7/2001–6/2004
Jonathan Oh, 7/2001–6/2004
Christine Lee, 7/2001–6/2005
Michael Frumovitz, 7/2001–6/2005
Sachin Apte, 7/2001–6/2005
Brian Slomovitz, 7/2002–6/2006
David Crotzer, 7/2002–6/2006
Premal Thaker, 7/2002–6/2006
Salvador Saldivar, 7/2003–6/2006
Charles Landen, 7/2003–6/2007
Pamela Soliman, 7/2003–6/2007
Aparna Kamat, 7/2004–6/2008
Kathleen Schmeler, 7/2004–6/2008
Liz Han, 7/2004–6/2008
Michael Milam, 7/2005–6/2009
William Merritt, 7/2005–6/2009
Yvonne Lin, 7/2005–6/2009
John Moroney, 7/2006–6/2010
Robin Lacour, 7/2006–6/2010
Shannon Westin, 7/2006–6/2010
Whitney Spannuth, 7/2006–6/2010
Alpa Nick, 7/2007–6/2011
Celestine Tung, 7/2007–6/2011
Larissa Meyer, 7/2007–6/2011
Jennifer Kelly Burzawa, 7/2008–6/2012
Matthew Peter Schlumbercht, 7/2008–6/2012
Rebecca Lynn Stone, 7/2008–6/2012

Other Supervisory Teaching

Julie Huh, 4th year medical student, Graduate Students, 1996
Lisa Bazzett, Clinical Residents and Fellows, 1997

Mentor, Global Academic Programs - University Hospital Juan Canalejo, Spain, Ovidio Fernandez-Calvo, MD, Foreign Visitor, 2/2009–5/2009

Mentor, Sister Institution Associates - Fudan Cancer Hospital, China, Global Academic Programs, Jie Tang, MD, Foreign Visitor, 6/2009–12/2009

Teaching Outside of Current Institution**Formal Teaching****Courses Taught**

Current Directions in Cancer Therapy & Research, National Ovarian Cancer Coalition

Yearly, 1998–present

A-Z Gene Therapy Replacing p53 to achieve antitumor effect, Society of Gynecologic Oncologists

Lecturer, Gene Therapy for Gynecologic Malignancies, University of Texas Medical School

Supervisory Committees

PhD Committee, Lee Seabrooke, Arizona State University, Tempe, AZ

CONFERENCES AND SYMPOSIA**Organization of Conferences/Symposia (Include chairing session)**

N/A

Presentations at National or International Conferences**Invited**

Characterization of two populations of the human ovarian cancer cell line, 2774, that express different levels of epidermal growth factor receptor, AACR Annual Meeting, 1993

Characterization of two populations of the human ovarian cancer cell line, 2774, that express different levels of epidermal growth factor receptor, Felix Rutledge Society Annual Meeting, 1993
Enhanced c-erbB-2/neu expression in human ovarian cancer cells correlates with more severe malignancy that can be suppressed by E1A, American Radium Society Annual Meeting, Aruba, 1993
Relationship between expression of c-erb2/neu and the malignant phenotype of a human ovarian cancer cell line (SK0V3), Felix Rutledge Society Annual Meeting, 1993
Expression of adenovirus β -galactosidase in rhesus monkey cervix and growth inhibition of human cervical cancer cells by recombinant p53, Felix Rutledge Society Annual Meeting, 1995
Growth inhibition of human cervical cancer cells by the recombinant adenovirus-mediated transfer of a wild-type p53 gene, Society of Gynecologic Oncologists 26th Annual Meeting, San Francisco, CA, 1995
The significance of cone biopsy margins in patients with adenocarcinoma in situ of the cervix, Felix Rutledge Society Annual Meeting, 1995
A-Z Gene Therapy - Replacing p53 to achieve antitumor effect, Society of Gynecologic Oncologist, 1997
Growth inhibition of human ovarian cancer cells by combination treatment with cisplatin and transfection with adenovirus-mediated p53, Society of Gynecologic Oncologists 28th Annual Meeting, Phoenix, AZ, 1997
Replacing p53 to Achieve an Antitumor Effect, Society of Gynecologic Oncologist 28th Annual Meeting, Phoenix, AZ, 1997
Growth suppression of human ovarian cancer cell lines by the introduction of a P16 via a recombinant adenovirus, Society of Gynecologic Oncologists Annual Meeting, 1998
Cirugia Citorreductora VS Cirugia Minimay uimioterapia Adyuvante, Sociedad Venezolana De Oncologia, VIII Congreso Venezolano De Oncologia, Puerto La Cruz, Venezuela, 10/9/1998
Ganglio Centinela En El Manejo Del Cancer Vulva, Sociedad Venezolana De Oncologia, VIII Congreso Venezolano De Oncologia, Puerto La Cruz, Venezuela, 10/9/1998
Principios De Terapia Genetica Aplicados A Oncologia Media, Sociedad Venezolana De Oncologia, VIII Congreso Venezolano De Oncologia, Puerto La Cruz, Venezuela, 10/9/1998
Terapia Genetica En Cancer, Sociedad Venezolana De Oncologia, VIII Congreso Venezolano De Oncologia, Puerto La Cruz, Venezuela, 10/9/1998
Gene Therapy for Gynecologic Malignancies, Department of Gynecology Grand Rounds, University of Texas Medical School, Houston, TX, 9/28/1999
A phase I trial of ADP53 for ovarian cancer patients: Correlation with p53 and anti-adenovirus AB status, Society of Gynecologic Oncologist Annual Meeting, 2000
A Phase I Trial of Adp53 for Patients with Platinum- and Paclitaxel-Resistant Epithelial Ovarian Cancer, 31st Annual Meeting of the Society of Gynecologic Oncologists, San Diego, CA, 2/9/2000
Prognostic Factors in Endometrial Cancer, Society of Gynecologic Oncologists 2000 Winter Meeting, Park City, UT, 3/18/2000
Effect of Transfecting P16 & P53 Suppressors on Cell Growth and Apoptosis in Ovarian Cancer Cell Lines, American Association for Cancer Research, 91st Annual Meeting, San Francisco, CA, 4/1/2000
Womens Professional Development, Association of American Medical Colleges Professional Development Seminar for Junior Women Faculty, Association of American Medical Colleges, Reston, VA, 4/1/2000
A Phase I Trial of Adp53 (RPR/INGN 201) for Ovarian Cancer Patients: Correlation with P53 and Anti-Adenovirus Antibody Status, American Society of Clinical Oncology, New Orleans, LA, 5/22/2000
Gene Therapy in Patients with Epithelial Ovarian Cancer, Gynecologic Oncology Group, 7/2000
Application of Molecular Biology in Gynecologic Cancer, Annual Meeting of the Thai Gynecologic Oncology Group, Nakorn Nayok, Thailand, 8/12/2000
The Role of Liposomal Doxorubicin (Caelyx) in Ovarian Cancer, Annual Meeting of the Thai Gynecologic Oncology Group, Nakorn Nayok, Thailand, 8/12/2000
Gene Therapy for Cervical Cancer - An Update, 2nd Annual International Conference on Cervical Cancer, Houston, TX, 4/13/2002
In Vivo Adenovirus-Mediated p16 Tumor Suppressor Gene Therapy in Ovarian Cancer, Texas Forum on Female Reproduction 8th Annual Meeting, Houston, TX, 5/2/2002
A Phase II Study of Xeloda in Patients with Chemotherapy Resistant Recurrent Ovarian Cancer, ASCO 2002 Annual Meeting, Orlando, FL, 5/19/2002
The Role of Docetaxel in Gynecologic Malignancies, 40th Japanese Society of Clinical Oncology Annual Meeting, Juntendo University, Toyko, Japan, 10/16/2002
Management of Ovarian cancer in the 21st Century-Surgery, Chemotherapy, and Molecular Therapy, 40th Japanese Society of Clinical Oncology Annual Meeting, Jutendo University, Toyko, Japan, 10/17/2002
Surgical Management of Gynecologic Malignancies, 40th Japanese Society of Clinical Oncology Annual Meeting, Jutendo University, Toyko, Japan, 10/17/2002
A Phase I/II Study to Evaluate the Optimum Biologic Dose of PEG-Intron in Patients with Platinum-Resistant Ovarian, Peritoneal, or Fallopian Tube Cancer, 11th SPORE Investigators Workshop, Baltimore, WA, 7/8/2003
A Phase I/II Study to Evaluate the Optimum Biologic Dose of PEG-Intron in Patients with Platinum-Resistant Ovarian, Peritoneal, or Fallopian Tube Cancer, 11th SPORE Investigator's Workshop, Baltimore, MD, 7/9/2003
P53 Targeted Therapy, 4th International Ovarian Cancer Conference, MSKCC, New York, NY, 9/11/2003
mTOR inhibition is a rational target for the treatment of endometrial cancer, ASCO 40th Annual Meeting, New Orleans, LA, 6/5/2004
Cervical and Endometrial Cancers - Preferred Treatment and Management Options, CME Conference, Hoag Cancer Center, Huntington Beach, CA, 1/28/2005
Health issues and risk factors for Breast and Gynecologic Cancers, Hadassah Check it Out program, San Antonio, TX, 2/9/2005
Cervical Cancer, Ovarian Cancer:What We Need to Know, Women's Health On Alert, Wellesley College, Wellesley, MA, 4/2/2005
Wiley, Miryam (Townsmen Correspondent) Women and hormonal health the expert views., The Wellesley Townsmen: townonline.com, Wellesley College, Wellesley, MA, 4/7/2005
Transitioning from Fellow to Faculty: How to go About Setting up an Independent Laboratory, and How to be a Mentor for Students, Residents and Fellows, 2005 Southern Regional Professional Development Conference - Successful Strategies for Women in Academic Medicine, Little Rock, AR, 4/16/2005
The Role of COUP-TFII in Ovarian Cancer, Grand Rounds, Baylor College of Medicine, Houston, TX, 5/6/2005
Biologic Therapies Should be Used as Single Agents in Ovarian Cancer Clinical Trials, Felix Rutledge Society 36th Annual Meeting, Mackinac Island, MI, 7/15/2005
Surgical Treatment of Ovarian Cancer Indications and Advances in the 21st Century, Chinese Society of Gynecologic Oncology, Tsinghua University, Nanjing, China, 6/3/2006

Surgical Treatment of Ovarian Cancer Indications and Advances in the 21st Century and Beyond, International Forum on the Mechanisms and Management of Ovarian Cancer, Peking University People's Hospital, Beijing, China, 6/9/2006
Thymidine Kinase Inhibitors in Gynecologic Malignancies, Felix Rutledge Society 36th Annual Meeting, Berlin, Germany, 9/7/2006
Intraperitoneal Chemotherapy for Optimally Debulked Ovarian Cancer and Emerging Therapies in Ovarian Cancer, 6th Samsung Medical Center - M. D. Anderson Cancer Center International Symposium, Seoul, Korea, Republic of, 11/4/2006
Ovarian Carcinoma for the General Oncologist, Third Symposium, Pursuit of Excellence: Addressing Issues and Trend in Oncology Nursing, UT M D Andersons Physicians Network, Santa Barbara, CA, 7/13/2007
Early Detection and Treatment of Ovarian Cancer, SGO, Tampa, FL, 3/9/2008
Optimizing Treatment Choices in Ovarian Cancer, SGO, Tampa, FL, 3/9/2008
Advances in the Management of Ovarian Stromal Tumors, ASCO, Chicago, IL, 5/31/2008
Ovarian Cancer, Uterine Cancer, Cervical Cancer, Hospital Israelita Albert Einstein and M D Anderson Cancer Center, Hospital Israelita Albert Einstein and M D Anderson Cancer Center, Sao Paulo, Brazil, 6/17/2008
Minimally Invasive Surgery in Gynecology Oncology, II International Symposium of Gynecology Oncology - Hospital Sírio-Libanês, São Paulo, Brazil, 11/7/2008
Gene Therapy and Targeted Therapies in Gynecologic malignancies, II International Symposium of Gynecology Oncology - Hospital Sírio-Libanês, São Paulo, Brazil, 11/8/2008
Gynecologic Cancers.What you need to know about Ovarian, Uterine, and Cervix Cancers, Albert Einstein Instituto Israelita De Ensino E Pesquisa, São Paulo, Brazil, 6/23/2009
Course Director, 8th International Conference on Ovarian Cancer, Memorial Sloan-Kettering Cancer Center, New York, NY, 9/24/2009
Treatment of Ovarian Cancer 21st Century and Beyond, 6th Chinese Conference on Oncology and the 9th Cross-Strait Conference on Oncology, Fudan University Shanghai Cancer Center, Shanghai, China, 5/21/2010
Chemotherapy Session Moderator, The 9th International Conference on Ovarian Cancer, Houston, TX 12/2/2011

Scientific Exhibitions

Current Directions in Cancer Therapy & Research, Cancer in Women: A Comprehensive Scientific Symposium on the Gynecologic Malignancies, National Ovarian Cancer Coalition, San Diego, CA, 2/4/2000
The Role of Gemcitabine in Ovarian Cancer, Lilly Oncology Advisory Meeting, Indianapolis, IN, 2/28/2002
Current and New Treatment Strategies for Ovarian Cancer, Grand Rounds, University of Medicine & Dentistry of New Jersey, Newark, NJ, 3/27/2002
Challenging Cases in Gynecologic Oncology, Network for Oncology Communication & Research, Las Vegas, NV, 8/17/2002
Cancer in Women: A scientific update in prevention, screening, treatment and risk management for ovarian and cervical malignancies, National Ovarian Cancer Coalition, Inc., Boston, MA, 10/10/2002
Ethical Delima's in Clinical Trials, John J. Molitar Lectureship CME Conference, University of California, Irvine, CA, 10/30/2002
The Application of Gene Therapy for Gynecologic Malignancies, Texas Medical Center Gene Therapy Symposium, Houston, TX, 11/11/2002
Indication for and Value of Screening for Ovarian Cancer, CME Conference, Inova Institute of Research & Education, Fairfax, VA, 11/15/2002
Treatment of recurrent Ovarian Cancer, Grand Rounds, Walter Reed Army Medical Center, Bethesda, MD, 12/4/2002
Current Treatment Strategies for Gynecologic Cancers, SGO Symposium 34th Annual Meeting, New Orleans, LA, 2/2/2003
Panel Physician - Ovarian Cancer Panel, The National Comprehensive Cancer Network on Ovarian Cancer Panel, Chicago, IL, 2/7/2003
Novel Therapeutics for Endometrial Cancer, 2003 SGO Winter Meeting, Breckenridge, CO, 3/7/2003
Novel Approaches to the Treatment of Gynecological Cancer, 2003 Oncology Forum, Fox Chase Cancer Center, Philadelphia, PA, 4/26/2003
Satellite Broadcast, Highlights from ASCO 2003, American Academy of the CME, Inc., Newark, NJ, 6/18/2003
What's New in Ovarian Cancer Treatment, NOCC National Conference, Ft. Lauderdale, FL, 11/8/2003
Ovarian Cancer: A Progress Report, 4th Annual Primary Care and Prevention conference, Atlanta, GA, 10/25/2004
Current & New Treatments for Ovarian Cancer, NOCC Conference, Philadelphia, PA, 10/30/2004
Clinical Trials, NOCC National Meeting, Ft. Lauderdale, FL, 11/13/2004
Cancer In Women: a Scientific Update on Ovarian Cancer-Prevention, Screening and Treatment, CME Conference, CME Massachusetts Medical Society & NOCC, 2/4/2005
Phase II Trials among the Ovarian SPORE Programs, Ovarian State of the Science Meeting - GOG Retreat, Bethesda, MD, 9/15/2005
Challenging Cases in Women's Health Recurrent Ovarian Cancer at 8 Months, NMCR Challenging Cases in Gyn Oncology and Breast Cancer, Miami, FL, 6/17/2006
How to Survive and Thrive as a Female Physician in Gynecologic Oncology, Japanese Society of Gynecologic Oncology 42nd Annual Meeting, Toyko, Japan, 6/28/2007
What's New Gynecologic Oncology? An Update on Translational and Clinical Research, Japanese Society of Gynecologic Oncology 42nd Annual Meeting, Toyko, Japan, 7/2/2007
Ovarian Carcinoma for the General Oncologist, UT M D Anderson Cancer Center and M D Anderson Physicians Network 3rd Annual Symposium

The University of Texas MD Anderson Cancer Center, Santa Barbara, CA, 7/9/2007 Ovarian Expert Recap - Clinical Options, ASCO, Chicago, IL, 5/30/2008 Controversial Issues in Recurrent Ovarian Cancer, Felix Rutledge Society Meeting, Buenos Aires, Argentina, 4/29/2009

Conversations with Oncology Investigators, Bridging the Gap between Research and Patient Care, Research to Practice CME Program, 01/2013

National Seminar Invitations

Attended, Association of American Medical Colleges Professional Development Seminar for Junior Women Faculty. Reston, Virginia, April 1-4, 2000

Gynecologic Cancers 2003 Treatment Update, CHRISTUS Spohn Shoreline Tumor Conference-CME, CHRISTUS Spohn Shoreline, Corpus Christi, TX, 8/27/2003

Update in the Management of Ovarian Cancer, Symposium on Women's Cancer, The Cleo Craig Memorial Cancer and Research Clinic, Lawton, OK, 8/28/2004

Palliative Care Issues for Patients Facing Advanced Ovarian Cancer, MDACC Physicians Network, Christus Schumpert Cancer CME Symposium, MDACC Physicians Network, Christus Schumpert Cancer CME Symposium, Shreveport, LA, 10/22/2004

PV, The Abnormal Pap Smear, and Cervical Cancer, MDACC Physicians Network, Christus Schumpert Cancer CME Symposium, MDACC Physicians Network, Christus Schumpert Cancer CME Symposium, Shreveport, LA, 10/22/2004

Metastatic Cervical Cancer, Cancer 2005: Preferred Treatment and Management Options, Hoag Cancer Center CME Oncology Meeting, Huntington Beach, CA, 1/28/2005

Recurrent Endometrial Cancer, Cancer 2005: Preferred Treatment and Management Options, Hoag Cancer Center CME Oncology Meeting, Huntington Beach, CA, 1/28/2005

Clinical Trials - Understanding, Navigating & Accessing Clinical Trials, Georgia Ovarian Cancer Awareness Conference, Georgia Ovarian Cancer Awareness Conference, Atlanta, GA, 2/19/2005

Cervical Cancer, Ovarian Cancer: What We Need to Know, Women's Health on Alert, Wellesley College, Wellesley, MA, 4/2/2005

Recurrent Endometrial Cancer Case#5, Challenging Cases in Women's Health, NOCR, Las Vegas, NV, 8/6/2005

Breaking Sound Barriers: Cutting Edge Research from the Lab and Clinical Trials, Turn the Volume Up-Ovarian Cancer National Alliance Conference, NOCC, Atlanta, GA, 9/29/2005

Clinical Trials 101, Turn the Volume Up-Ovarian Cancer National Alliance Conference, NOCC, Atlanta, GA, 9/29/2005

Risk Factors and Genetic Risk factors Regarding Ovarian Cancer, Diagnosis and Treatment of Ovarian Cancer - Beyond Chemotherapy National Ovarian Cancer Coalition Symposium, NOCC, Philadelphia, PA, 10/29/2005

Clinical Trials, National Ovarian Cancer Coalition Mini-Conferences, NOCC, Silver Springs, MD, 11/12/2005

Current & New Treatments for Ovarian Cancer, Grand Rounds, Advocate Christ Medical Center, Oak Lawn, IL, 1/12/2006

Progress and Treatment for Ovarian Cancer, Grand Rounds CME, MacNeal Hospital, Berwyn, IL, 4/25/2006

Women and Cancer: A Focus on Cervical and Ovarian Cancer, Oncology Nursing and Pharmacy Conference Series 2006: Collaboration for Advancing the Quality of Community Cancer Care, UTMB Office of Continuing Education, San Diego, CA, 11/18/2006

Women and Cancer: A Focus on Cervical and Ovarian Cancer, Oncology Nursing and Pharmacy Conference Series 2006: Collaboration for Advancing the Quality of Community Cancer Care, UTMB Office of Continuing Education, Williamsburg, VA, 12/2/2006

Future Directions and New Frontiers in Individualized Therapeutic Approaches, SGO-CME Certified Satellite Symposium Management of Recurrent Epithelial Ovarian Cancer: Current Standards and Novel Approaches, Society of Gynecologic Oncologist, San Diego, CA, 3/5/2007

Treatment of a Patient with Recurrent, Platinum-Resistant Disease, SGO-CME Certified Satellite Symposium Management of Recurrent Epithelial Ovarian Cancer: Current Standards and Novel Approaches, Society of Gynecologic Oncologist, San Diego, CA, 3/5/2007

Northwestern Prentice Women's Hospital, Guest Speaker, Chicago, IL. 02/08/2008 "From Bench to Bedside – My Personal Experience

Texas Medical Association, Ovarian Cancer Advisory Panel Meeting, Austin, TX, July 21, 2008

EIF Callaway Golf Foundation Women's Cancer Initiative Annual Meeting, "Ovarian Cancer Research Program", Carlsbad, CA, August 8, 2008

The Impact of Stress, Gynecologic Cancer Foundation, NYU Langone Medical Center, New York, NY, 11/1/2008

Global Academic Programs (formerly Sister Institution Conference MDACC), Chair the Working Group on Gynecologic Malignancies, Houston, TX, 6/6/2008

MD Anderson Cancer Center Development Symposium, accompanied Dr. Mendelsohn and spoke at the Southern Hills Country Club, Tulsa, OK, June 24, 2008

Gastrointestinal Cancer Retreat and PI3K Workshop: CCSG Programs Onstead Auditorium, BSRB Mitchell Building

Advisor, Entereg Complex Gynecologic Surgery Advisory Meeting, GSK, Philadelphia, PA, December 5-6, 2008

Texas Medical Association, Ovarian Cancer Advisory Panel Meeting, Austin, TX, January 9, 2009

Advisor, Yondelis Advisory Board Meeting, Centocor Ortho Biotech, Newport Beach, CA, February 20-21, 2009

Texas Medical Association, Ovarian Cancer Advisory Panel Meeting, Austin, TX, July 14, 2009

Career Pathways for Women in Science and Medicine & What the Careers of the Future Will Hold and More, Dinner with the Experts, Spring Branch Independent School District, Houston, TX, January 21, 2010

Faculty, CE-Continuing Education Program, OncoBeat ASCO 2010: Reporting the News. Beating Cancer. Educational Concepts Group, LLC; Chicago, IL; June 7, 2010.

Advanced Ovarian Cancer, Facilitator for Interactive Case Discussions, SGO, March 26, 2012

Guest Speaker, "The Ethics of Clinical Trials", Phoenix Chapter of Associa of Clinical Research Professionals, July 2013

Lectureships/Visiting Professorships

Gynecologic Oncology Overview, Grand Rounds, Beaumont Hospital, Beaumont, TX, 4/17/1997

Abnormal Uterine Bleeding & Endometrial Cancer, Grand Rounds, St. Frances Cabrini Hospital, Alexandria, LA, 8/24/1999

Gynecologic Oncology Overview, Grand Rounds, Nacogdoches/San Augustine Medical Society, Nacogdoches, TX, 11/10/1999

Gene Therapy for Gynecologic Malignancies, University of Minnesota Fellowship Program, Minneapolis, MN, 12/14/1999

Gynecologic Cancers: Diagnosis, Treatment & Outcomes-Where We've Been & Where We're Going, Grand Rounds, Christus Spohn Health System Tumor Conference, Corpus Christi, TX, 9/20/2000

Current and New Treatment Strategies for Ovarian Cancer, CME, University of Medicine & Dentistry of New Jersey, Medical School, Newark, NJ, 3/27/2002

Ethical Delima's in Clinical Trials, John J. Molitar Lectureship, University of California, Irvine, CA, 10/30/2002

The Application of Gene Therapy for Gynecologic Malignancies, Texas Medical Center Gene Therapy Symposium, Texas Medical Center, Houston, TX, 11/11/2002

Indication for and Value of Screening for Ovarian Cancer, CME, Inova Institute of Research & Education, Fairfax, VA, 11/15/2002

Treatment of recurrent Ovarian Cancer, CME, Walter Reed Army Medical Center, Bethesda, MD, 12/4/2002

Novel Therapeutics for Endometrial Cancer, 2003 SGO Winter Meeting, Society of Gynecologic Oncologist, Breckenridge, CO, 3/7/2003

Physician Advisor for Gynecological Cancer Advisory Board, Novel Approaches to the Treatment of Gynecological Cancer, 2003 Oncology Forum, Fox Chase Cancer Center, Philadelphia, PA, 4/26/2003

Translational Research from Bench to Bedside One Gynecologic Oncologist's Experience, Bench to Beside Symposium, NYU Medical Center, New York, NY, 5/20/2005

Progress and Treatment of Ovarian Cancer, MDACC Faculty Speakers Bureau, CME - OB/GYN Grand Rounds, St. David's Healthcare, Austin, TX, 10/18/2005

Progress and Treatment of Ovarian Cancer, MDACC Faculty Speakers Bureau, CME - University Hospital Grand Rounds, University Health Care System, Augusta, GA, 10/20/2005

Current and New Treatments for Ovarian Cancer, CME, Advocate Christ Hospital, Oak Lawn, IL, 1/12/2006

The Ethics of Clinical Trials, University of Minnesota Gynecologic Oncology Consensus Conference, University of Minnesota, Minneapolis, MN, 5/8/2006

Comprehensive Management of Ovarian Cancer: Current Treatment and Maximizing Quality of Life, CME-Medical Communications Media, Novato Community Hospital, Novato, CA, 5/7/2007

Comprehensive Management of Ovarian Cancer: Current Treatment and Maximizing Quality of Life, Grand Rounds-Medical Communications Media, University of Pittsburgh, Pittsburgh, PA, 6/5/2007

Treatment of Ovarian Cancer - 21st Century and Beyond, Grand Rounds, UC Davis Medical Center, Gynecologic Oncology, Sacramento, CA, 12/17/2008

Gynecologic Cancers: Uterine Cancer, CME: Update on Endometrial Cancer, Citizens Medical Center, Office of Continuing Medical Education, Victoria, TX, 1/11/2010

NATIONAL CONFERENCES- INVITED/ AND OR SPEAKER

Treatment of Ovarian Cancer, National Ovarian Cancer Coalition State Chapters Meeting, NOCC, Ft. Lauderdale, FL, 11/5/1999

Commencement speaker, East Liverpool High School, East Liverpool, OH, 6/1/2000

Gynecologic Cancers: Diagnosis, Treatment & Outcomes-Where We've Been & Where We're Going, 2nd Annual "Closing Gaps & Opening Doors Conference for Working Women, U.S. Department of Labor, Women's Bureau Region VI, Austin, TX, 10/5/2000

Talk-back Session - Moderator, Wet State Theater, Alley Theater, UT M D Anderson Cancer Center & the Stanford Foundation, Austin, TX, 5/31/2001

Interferon-g in the Management of Ovarian Cancer clinical Advisory Program, Advisory Program, InterMune Pharmaceuticals, Houston, TX, 6/21/2001

Current & New Treatments for Ovarian Cancer, Cancer in Women: A Scientific Update in Prevention, Screening and Treatment for Ovarian Cancer, NOCC, Houston, TX, 1/1/2004

Management of Gynecologic Cancer, Sanofi-Synthelabo Oncology Health Science Advisory Board Meeting, Sanofi-Synthelabo Oncology, Dallas, TX, 4/24/2004

Controversies in Ovarian Cancer, ACOG Update, Audiotaped Tele-Conference, ACOG, Houston, TX, 5/14/2004

Health issues and risk factors for Breast and Gynecologic Cancers, Hadassah Check it Out program to educate young women in Houston Independent School District, Worthing High School, Houston, TX, 2/9/2005

Screening for Gynecologic Cancers, CME Memorial Hermann Southwest Hospital, Memorial Hermann Southwest Hospital, Houston, TX, 3/8/2005

The Role of COUP-TFII in Ovarian Cancer, Arthur M. Faris, Sr., MD Resident Research Day, Baylor College of Medicine, Obstetrics and Gynecology, Houston, TX, 5/6/2005

Menopause The Musical Out Loud - Breaking the Silence on Ovarian Cancer, National Ovarian Cancer Coalition, Matrix Graphix, and Ovarian Cancer National Alliance Aging Out Loud Tour, TOC Productions Inc., www.menopausethemusical.com, National Ovarian Cancer Coalition, Stafford, TX, 3/3/2006

Progress and Treatment of Ovarian Cancer, National Ovarian Cancer Coalition, American Cancer Society, National Ovarian Cancer Coalition, American Cancer Society, Austin, TX, 3/20/2006

What you need to know - Hereditary Breast and Ovarian Cancer, UT M D Anderson Cancer Center and The San Antonio Chapter of Hadassah, San Antonio, TX, 10/26/2006

Progress and Treatment for Ovarian Cancer, UTMB - CME Grand Rounds, Galveston, TX, 2/14/2007

Moderator - Stump the Professor, 37th Annual Meeting of the Felix Rutledge Society, Houston, TX, 6/13/2007

Ovarian Cancer Advisory Panel, Physician Oncology Education Program, Ovarian Cancer Advisory Panel Meeting, Texas Medical Association, Austin, TX, 12/10/2007

Cervical Cancer Update Including the Role of Vaccines, SGO-Society of Gynecologic Oncologist, Educational Concepts Group, LLC, Oncobeat SGO: Reporting the News.Beatting Cancer, San Antonio, TX, 2/8/2009

Wolf, JK. Strategies for the Management of Platinum-Resistant Ovarian Cancer, 41st Annual Meeting on Women's Cancer Society of Gynecologic Oncologist, CBCE - University of North Texas Health Science Center at Fort Worth, Center for Biomedical Continuing Education, San Francisco, CA, 3/15/2010

Ovarian Cancer, Women's Cancer Awareness Conference, Methodist Healthcare System, San Antonio, TX, 9/30/2010

Gynecologic Oncology Overview, Grand Rounds, Beaumont Hospital, Beaumont, TX, 4/17/1997 Abnormal Uterine Bleeding & Endometrial Cancer, Grand Rounds, St. Frances Cabrini Hospital, Alexandria, LA, 8/24/1999

Gynecologic Oncology Overview, Grand Rounds, Nacogdoches/San Augustine Medical Society, Nacogdoches, TX, 11/10/1999

Gene Therapy for Gynecologic Malignancies, University of Minnesota Fellowship Program, Minneapolis, MN, 12/14/1999

Gynecologic Cancers: Diagnosis, Treatment & Outcomes-Where We've Been & Where We're Going, 2nd Annual "Closing Gaps & Opening Doors Conference for Working Women, U.S. Department of Labor, Women's Bureau Region VI, Austin, TX, 10/5/2000

Gynecologic Cancers: Diagnosis, Treatment & Outcomes-Where We've Been & Where We're Going, Grand Rounds, Christus Spohn Health System Tumor Conference, Corpus Christi, TX, 9/20/2000

Talk-back Session - Moderator, Wet State Theater, Alley Theater, UT M D Anderson Cancer Center & the Stanford Foundation, Austin, TX, 5/31/2001

Interferon-g in the Management of Ovarian Cancer clinical Advisory Program, Advisory Program, InterMune Pharmaceuticals, Houston, TX, 6/21/2001

Current and New Treatment Strategies for Ovarian Cancer, CME, University of Medicine & Dentistry of New Jersey, Medical School, Newark, NJ, 3/27/2002

Ethical Delima's in Clinical Trials, John J. Molitar Lectureship, University of California, Irvine, CA, 10/30/2002

The Application of Gene Therapy for Gynecologic Malignancies, Texas Medical Center Gene Therapy Symposium, Texas Medical Center, Houston, TX, 11/11/2002

Indication for and Value of Screening for Ovarian Cancer, CME, Inova Institute of Research & Education, Fairfax, VA, 11/15/2002

Treatment of recurrent Ovarian Cancer, CME, Walter Reed Army Medical Center, Bethesda, MD, 12/4/2002

Novel Therapeutics for Endometrial Cancer, 2003 SGO Winter Meeting, Society of Gynecologic Oncologist, Breckenridge, CO, 3/7/2003

Physician Advisor for Gynecological Cancer Advisory Board, Novel Approaches to the Treatment of Gynecological Cancer, 2003 Oncology Forum, Fox Chase Cancer Center, Philadelphia, PA, 4/26/2003

Current & New Treatments for Ovarian Cancer, Cancer in Women: A Scientific Update in Prevention, Screening and Treatment for Ovarian Cancer, NOCC, Houston, TX, 1/1/2004

Management of Gynecologic Cancer, Sanofi-Synthelabo Oncology Health Science Advisory Board Meeting, Sanofi-Synthelabo Oncology, Dallas, TX, 4/24/2004

Controversies in Ovarian Cancer, ACOG Update, Audiotaped Tele-Conference, ACOG, Houston, TX, 5/14/2004

Health issues and risk factors for Breast and Gynecologic Cancers, Hadassah Check it Out program to educate young women in Houston Independent School District, Worthing High School, Houston, TX, 2/9/2005

Screening for Gynecologic Cancers, CME Memorial Hermann Southwest Hospital, Memorial Hermann Southwest Hospital, Houston, TX, 3/8/2005

The Role of COUP-TFII in Ovarian Cancer, Arthur M. Faris, Sr., MD Resident Research Day, Baylor College of Medicine, Obstetrics and Gynecology, Houston, TX, 5/6/2005

Translational Research from Bench to Bedside One Gynecologic Oncologist's Experience, Bench to Beside Symposium, NYU Medical Center, New York, NY, 5/20/2005

Progress and Treatment of Ovarian Cancer, MDACC Faculty Speakers Bureau, CME - OB/GYN Grand Rounds, St. David's Healthcare, Austin, TX, 10/18/2005

Progress and Treatment of Ovarian Cancer, MDACC Faculty Speakers Bureau, CME - University Hospital Grand Rounds, University Health Care System, Augusta, GA, 10/20/2005

Current and New Treatments for Ovarian Cancer, CME, Advocate Christ Hospital, Oak Lawn, IL, 1/12/2006

Menopause The Musical Out Loud - Breaking the Silence on Ovarian Cancer, National Ovarian Cancer Coalition, Matrix Graphix, and Ovarian Cancer National Alliance Aging Out Loud Tour, TOC Productions Inc., www.menopausethemusical.com, National Ovarian Cancer Coalition, Stafford, TX, 3/3/2006

Progress and Treatment of Ovarian Cancer, National Ovarian Cancer Coalition, American Cancer Society, National Ovarian Cancer Coalition, American Cancer Society, Austin, TX, 3/20/2006

The Ethics of Clinical Trials, University of Minnesota Gynecologic Oncology Consensus Conference, University of Minnesota, Minneapolis, MN, 5/8/2006

What you need to know - Hereditary Breast and Ovarian Cancer, UT M D Anderson Cancer Center and The San Antonio Chapter of Hadassah, San Antonio, TX, 10/26/2006

Progress and Treatment for Ovarian Cancer, UTMB - CME Grand Rounds, Galveston, TX, 2/14/2007

Comprehensive Management of Ovarian Cancer: Current Treatment and Maximizing Quality of Life, CME-Medical Communications Media, Novato Community Hospital, Novato, CA, 5/7/2007

Comprehensive Management of Ovarian Cancer: Current Treatment and Maximizing Quality of Life, Grand Rounds-Medical Communications Media, University of Pittsburgh, Pittsburgh, PA, 6/5/2007

Moderator - Stump the Professor, 37th Annual Meeting of the Felix Rutledge Society, Houston, TX, 6/13/2007

Ovarian Cancer Advisory Panel, Physician Oncology Education Program, Ovarian Cancer Advisory Panel Meeting, Texas Medical Association, Austin, TX, 12/10/2007

Lecturer: Teal Lunch for Life, "Ovarian Cancer: Top Ten Questions What you really need to know..," benefiting Blanton-Davis Ovarian Cancer Research Program, San Antonio, TX, September 10, 2008

Lecturer: E2 Communications-Opinions in Gyn Malignancies: An Interactive Forum and KOL Focus Group, Las Vegas, NV, October 18, 2008

Treatment of Ovarian Cancer - 21st Century and Beyond, Grand Rounds, UC Davis Medical Center, Gynecologic Oncology, Sacramento, CA, 12/17/2008

Lecturer: Shell Health - Shell Oil Company, Prevention and Gynecological Oncology, Houston, TX, April 6, 2009

Lecturer: Raising Ovarian Cancer Awareness to Increase Survival Rates; NOCC, Media Blitz in New York, NY, April 22-23, 2009

Speaker, Teal Lunch for Life, "Ovarian Cancer: What you need to know and how you can help..," benefiting Blanton-Davis Ovarian Cancer Research Program, San Antonio, TX, Sept. 9, 2009

Speaker, Key to the Cure Benefit, "Ovarian Cancer, Raise Awareness"; NOCC & Saks 5th Avenue-Austin, Austin, TX, September 17, 2009

Cervical Cancer Update Including the Role of Vaccines, SGO-Society of Gynecologic Oncologist, Educational Concepts Group, LLC, Oncobeat SGO: Reporting the News.Beatting Cancer, San Antonio, TX, 2/8/2009

Gynecologic Cancers: Uterine Cancer, CME: Update on Endometrial Cancer, Citizens Medical Center, Office of Continuing Medical Education, Victoria, TX, 1/11/2010

Speaker, CME/CNE Ovarian Cancer Knowledge Video, Texas Medical Association, Ovarian Cancer Advisory Panel Meeting, Austin, TX, January 25, 2010

Wolf, JK. Strategies for the Management of Platinum-Resistant Ovarian Cancer, 41st Annual Meeting on Women's Cancer Society of Gynecologic Oncologist, CBCE - University of North Texas Health Science Center at Fort Worth, Center for Biomedical Continuing Education, San Francisco, CA, 3/15/2010

Ovarian Cancer, Women's Cancer Awareness Conference, Methodist Healthcare System, San Antonio, TX, 9/30/2010

PROFESSIONAL MEMBERSHIPS/ACTIVITIES

Professional Society Activities, with Offices Held

National and International

American Association of Cancer Research

Member, 1996-2014

Felix Rutledge Society

Member, 1996-present

Chairman, Program Committee, 1999

Co-Chairman, Program Committee, 2007

President, 2008-2009

Society of Gynecologic Oncology

Member, 1996-present

Member, Program Committee, 1999

Member, Government Relations Committee, 2002-2011

Co-Chair, Government Relations Committee, 2005-2011

American Society of Clinical Oncology

Member, 1997-present

American College of Obstetrics and Gynecology

Fellow, 1999-present

Gynecologic Oncology Group

Member, Developmental Therapeutics Committee, 2001-2011

Member, Phase I Subcommittee, 2004-2011

NEOMED Alumni Board

Rootstown, OH

Member 2008-2014

Southern Regional Professional Development Conference for Women in Medicine and Research, Take charge of Your Life: Speak Up, Stand Out, and Stay Calm

Member, Planning Committee, 3/2007

American Gynecological & Obstetrical Society

Fellow, 11/2007–present

Southwest Oncology Group (SWOG), Seattle, WA

Member, 11/2010–2011

Local/State

Houston Gynecology & Obstetrics Society, Houston, TX

Member, 1996

Treasurer, 1998–2000

Vice President, 2001–2002

President-Elect, 2002–2003

President, 2003–2004

Member, 2004–2011

Ob-Gyn Alumni Association, The University of Texas Health Science Center at San Antonio, San Antonio, TX

Member, 1999

American Board of Obstetrics & Gynecology, Dallas, TX

Oral Board Examiner, 12/2008

Oral Examiner, 12/2009

Examiner, 12/2010

MEDIA: LOCAL AND NATIONAL

1. News Article on Women's Health On Alert Conference: Wiley, Miryam (Townsmen Correspondent) Women and hormonal health - the expert views. The Wellesley Townsmen: townonline.com, April 7, 2005
2. Lecturer, Breaking the Silence on Ovarian Cancer - Diagnosis and Treatment; NOCC, State of Disease, Teleconference in Advance of Nation's Leading Cancer Meeting, Taped in New York, NY, Televised Live Across the Nation, May 22-23, 2006
3. Lecturer, Breaking the Silence on Ovarian Cancer - Diagnosis and Treatment; NOCC Media Initiative Magazine Interview, Interviewed in New York, NY, Fitness, MEDIZine's Healthy Living, Family Circle, Prevention, Cosmopolitan, Glamour, Woman's Day, O Magazine, March 11-13, 2007
4. Lecturer, Breaking the Silence on Ovarian Cancer Campaign, NOCC Media Alert Blitz on the Consensus of Ovarian Cancer; Teleconference in Advance of Nation's Leading Cancer Meeting, Taped in Houston, Texas, Televised Live Across the Nation, June 25, 2007
5. Dr. Oz Show appearance, Birth Control Pills and Risk of Ovarian Cancer, March 2012
6. I Heart Radio, "Preview of Highlights of San Antonio Breast Cancer Society Meeting", December 2013

COMMUNITY

1. Foundation Event – Development Reception for Banner MD Anderson Cancer Center, November 3, 2011
2. Foundation Event – Presentation at Vi Community, Scottsdale, Arizona 02/2012
3. Banner Health Foundation Lunch - JoAnn O'reffice, Pat McKennon and Pat Carbone Tour and Lunch, March 30, 2012
4. Foundation Event – Freeport McMoRan Employee Campaign Launch, Phoenix, AZ , April 6, 2012
5. Surgery Grand Rounds, Banner Good Samaritan Hospital, Gynecologic Oncology 2012 Updates, Phoenix, AZ, March 2012
6. Foundation Event – Bill and Anne Smith Reception, Sedona, AZ April 21, 2012
7. Foundation Event – Presentation at Vi Community, Scottsdale, Arizona 09/12/2012
8. Speaker at 4th Annual Run/Walk for Ovarian Cancer, Break the Silence, NOCC 09/23/2012
9. Speaker at Association of Physician Assistants in Oncology, 2012 Annual Conference, Scottsdale, AZ 10/13/2012
10. Obesity and Cancer, Banner Gateway Medical Center Bariatric Grand Rounds, 02/2013
11. Advanced Leadership Program for Physicians, Banner Health, 2012-2013
12. Principal-Investigator, Various Donors, UT M. D. Anderson Cancer Center, 1999-Present, \$324,834
13. Selected 2013 *Top 50 Most Influential Women in Business*

NATIONAL PROFESSIONAL LECTURES/TALKS

Lecturer: **Strengthening Her Fight in the Battle Against Ovarian Cancer; Physicians Connect-Tibotec (Doxil) Pharmaceuticals & MediMedia**

Houston, TX, October 11, 2005

Woodlands, TX October 12, 2005

Moline, IL, October 25, 2005

Monrovia, CA, October 27, 2005

Grand Rapids, MI, December 15, 2005

Kansas City, MO, January 10, 2006

Houston, TX, October 17, 2006

Oklahoma City, OK, November 14, 2006

Woodlands, TX, April 23, 2007

Oklahoma City, OK, May 8, 2007

Houston, TX, June 12, 2007

Houston, TX, June 19, 2007

Houston, TX (MDACC), June22, 2007

Houston, TX, October 17, 2007

Houston, TX, December 5, 2007

Houston, TX, June 6, 2008

Houston, TX, May 14, 2009

Lecturer: **Latest Developments in HPV-Related Diseases and Cervical Cancer; Merck i-Med Conference**

Lubbock, TX, September 26, 2006
Dallas, TX, October 10, 2006
Tyler, TX, October 24, 2006
Harvey, LA, November 16, 2006
Beaumont, TX, November 20, 2006
Snyder, TX, November 21, 2006
Bedford, TX, January 18, 2007
Denver, CO, January 30, 2007
Houston, TX, February 13, 2007
Baytown, TX, February 20, 2007
Houston, TX, March 14, 2007
Austin, TX, March 28, 2007
Arlington, TX, May 14, 2007
Houston, TX (MDACC), May 18, 2007
Webster, TX, May 23, 2007
Woodlands, TX, June 7, 2007
Dallas, TX, June 8, 2007
Chicago, IL, July 23, 2007
Nacogdoches, TX, October 30, 2007
Houston, TX, November 11, 2007
San Antonio, TX, November 14, 2007
Dallas, TX, December 4, 2007
Dallas, TX, December 14, 2007
Grapevine, TX, February 4, 2008
San Antonio, TX, February 18, 2008
San Angelo, TX, February 19, 2008
Nacogdoches, TX, February 28, 2008
Hutchinson, KS, May 12, 2008

Lecturer: **The Management of Cervical Cancer: Focus on Hycamtin; Advanced Communication and Education (ACE) - Glaxo Smith Klein (GSK)**

Beaumont, TX, October 30, 2006
Corpus Christi, TX, November 27, 2006
Lafayette, LA, November 28, 2006
Lake Charles, LA, April 2, 2007

Grand Rounds Speaker: **Comprehensive Management of Ovarian Cancer: Current Treatment and Maximizing Quality of Life; Medical Communications Media Bureau**

Casper, WY, September 11, 2007
Pensacola, FL, October 9, 2007
Sugarland, TX, November 9, 2007
Houston, TX, December 4, 2007
Victoria, TX, December 5, 2007
Birmingham, AL, April 1, 2008
Kansas City, MO, May 7, 2008
St. Petersburg, FL, August 21, 2008
Victoria, TX, December 3, 2008
Newport Beach, CA, December 4, 2008

Lecturer: **The Treatment of Platinum-Sensitive Advanced Ovarian Cancer; Lilly Lecturer Bureau**

Houston, TX, April 3, 2007
Harlingen, TX, 12pm & 7pm, Jan 31, 2008
McAllen, TX, March 26, 2008
Brownsville, TX, March 26, 2008
Jacksonville, FL, April 23, 2008
Houston, TX, May 5-6, 2008
Fort Worth, TX, May 14, 2008
Wichita Falls, TX, May 14, 2008
Houston, TX, May 15, 2008
San Antonio, TX, May 28, 2008
Houston, TX, June 4, 2008
San Antonio, TX, July 2, 2008
Beaumont, TX, July 23, 2008
Fort Worth, TX, August 27, 2008
Wichita Falls, TX, August 27, 2008
Indianapolis, IN, (3-talks), September 3, 2008
Corpus Christi, TX, September 17, 2008
Laredo, TX, September 17, 2008
San Antonio, TX, October, 22, 2008
Temple, TX, May 22, 2009
Laredo, TX, May 27, 2009
McAllen, TX, May 28, 2009
Houston, TX, June 4, 2009
Houston, TX, June 17, 2009
Beaumont, TX, August 6, 2009

Volunteer and Advocacy

1. Founder, Sprint for Life Fun Run, Raised over \$5 Million to Date For Ovarian Cancer Research, 1998-Present
2. National Ovarian Cancer Coalition- Member of medical advisory board 1996- 2008. Member of Governing Board 2009-present.
3. Society for Women's Health Research- Board Member 2014-present
4. Health Volunteers Overseas- 20-14- present. Volunteered in Viet Nam, Honduras, Haiti: Project Director Bhaktapur Nepal. Oncology Steering Committee Member.

CV updated; 01/05/2019

Judith K Wolf, MD

Exhibit B

Judith Wolf, M.D.
Materials Considered

1. "A Survey of the Long-Term Effects of Talc and Kaolin Pleurodesis." *British Journal of Diseases of the Chest* 73 (1979): 285–88.
2. Acencio, Milena M. P., Evaldo Marchi, Lisete R. Teixeira, Bruna Rocha Silva, Juliana Sanchez Silva, Carlos Sergio Rocha Silva, Vanessa Adelia Alvarenga, Leila Antonangelo, Francisco Suso Vargas, and Vera Luiza Capelozzi. "Talc Particles and Pleural Mesothelium Interface Modulate Apoptosis and Inflammation." *Pathology* 46, no. S2 (2014): S76.
3. Acheson, E D, M J Gardner, E C Pippard, and L P Grime. "Mortality of Two Groups of Women Who Manufactured Gas Masks from Chrysotile and Crocidolite Asbestos: A 40-Year Follow-Up." *British Journal of Industrial Medicine* 39, no. 4 (November 1982): 344–48.
4. ACOG. "Talc Use and Ovarian Cancer." Statements, September 11, 2017.
5. Akhtar, Mohd Javed, Maqsood Ahmed, M.A. Majeed Khan, Salman A. Alrokayan, Iqbal Ahmad, and Sudhir Kumar. "Cytotoxicity and Apoptosis Induction by Nanoscale Talc Particles from Two Different Geographical Regions in Human Lung Epithelial Cells." *Environmental Toxicology* 29 (2014): 394–406. <https://doi.org/10.1002/tox.21766>.
6. Akhtar, Mohd Javed, Sudhir Kumar, Ramesh Chandra Murthy, Mohd Ashquin, Mohd Imran Khan, Govil Patil, and Iqbal Ahmad. "The Primary Role of Iron-Mediated Lipid Peroxidation in the Differential Cytotoxicity Caused by Two Varieties of Talc Nanoparticles on A549 Cells and Lipid Peroxidation Inhibitory Effect Exerted by Ascorbic Acid." *Toxicology in Vitro: An International Journal Published in Association with BIBRA* 24, no. 4 (June 2010): 1139–47.
7. American Cancer Society. "Talcum Powder and Cancer." American Cancer Society, November 13, 2017.
8. Antoniou, A., et al. "Average Risks of Breast and Ovarian Cancer Associated with BRCA1 or BRCA2 Mutations Detected in Case Series Unselected for Family History: A Combined Analysis of 22 Studies." *American Journal of Human Genetics* 72, no. 5 (May 2003): 1117–30.
9. Amrhein, V., et al., "Retire statistical significance." *Nature*. 567 (2019): 305-307.
10. Arellano-Orden, Elena, Auxiliadora Romero-Falcon, Jose Martin Juan, Manuel Ocana Jurado, Francisco Rodriguez-Panadero, and Ana Montes-Worboys. "Small Particle-Size Talc Is Associated with Poor Outcome and Increased Inflammation in Thoracoscopic Pleurodesis." *Respiration* 86 (2013): 201–9. <https://doi.org/10.1159/000342042>.
11. "ATSDR - Toxicological Profile: Asbestos." Accessed August 16, 2018.
12. "ATSDR - Toxicological Profile: Silica." Accessed August 16, 2018.
13. Baldwin, Lauren A., Bin Huang, Rachel W. Miller, Thomas Tucker, Scott T. Goodrich, Iwona Podzielinski, Christopher P. DeSimone, Fred R. Ueland, John R. van Nagell, and Leigh G. Seamon. "Ten-Year Relative Survival for Epithelial Ovarian Cancer:" *Obstetrics & Gynecology* 120, no. 3 (September 2012): 612–18.
14. Balkwill, Fran, and Alberto Mantovani. "Inflammation and Cancer: Back to Virchow?" *The Lancet* 357, no. 9255 (February 2001): 539–45. [https://doi.org/10.1016/S0140-6736\(00\)04046-0](https://doi.org/10.1016/S0140-6736(00)04046-0).
15. Barnhart, K., et al. "Baseline Dimensions of the Human Vagina." *Human Reproduction* Vol. 21, no. 6 (2006): 1618-22.
16. Bartrip, P. W. J. "History of Asbestos Related Disease." *Postgraduate Medical Journal* 80, no. 940 (February 1, 2004): 72–76. <https://doi.org/10.1136/pmj.2003.012526>.
17. Beck, B. D., H. A. Feldman, J. D. Brain, T. J. Smith, M. Hallock, and B. Gerson. "The

Pulmonary Toxicity of Talc and Granite Dust as Estimated from an in Vivo Hamster Bioassay.” *Toxicology and Applied Pharmacology* 87, no. 2 (February 1987): 222–34.

18. Begg, Melissa D., and Dana March. “Cause and Association: Missing the Forest for the Trees.” *American Journal of Public Health* 108, no. 5 (May 2018): 620.
19. Belotte, Jimmy, Nicole M. Fletcher, Awoniyi O. Awonuga, Mitchell Alexis, Husam M. Abu-Soud, Ghassan M. Saed, Michael P. Diamond, and Mohammed G. Saed. “The Role of Oxidative Stress in the Development of Cisplatin Resistance in Epithelial Ovarian Cancer.” *Reproductive Sciences* 21, no. 4 (2014): 503–8. <https://doi.org/10.1177/1933719113503403>.
20. Belotte, Jimmy, Nicole M. Fletcher, Mohammed G. Saed, Mohammed S. Abusamaan, Gregory Dyson, Michael P. Diamond, and Ghassan M. Saed. “A Single Nucleotide Polymorphism in Catalase Is Strongly Associated with Ovarian Cancer Survival.” *PloS One* 10, no. 8 (2015).
21. Berge, Wera, Kenneth Mundt, Hung Luu, and Paolo Boffetta. “Genital Use of Talc and Risk of Ovarian Cancer: A Meta-Analysis.” *European Journal of Cancer Prevention*, January 2017, 1.
22. Berry, G., M. L. Newhouse, and J. C. Wagner. “Mortality from All Cancers of Asbestos Factory Workers in East London 1933–80.” *Occupational and Environmental Medicine* 57, no. 11 (November 2000): 782–85.
23. Bertolotti, Marinella, Daniela Ferrante, Dario Mirabelli, Mario Botta, Marinella Nonnato, Annalisa Todesco, Benedetto Terracini, and Corrado Magnani. “[Mortality in the cohort of the asbestos cement workers in the Eternit plant in Casale Monferrato (Italy)].” *Epidemiologia E Prevenzione* 32, no. 4–5 (October 2008): 218–28.
24. Blank, M M, N Wentzensen, M A Murphy, A Hollenbeck, and Y Park. “Dietary Fat Intake and Risk of Ovarian Cancer in the NIH-AARP Diet and Health Study.” *British Journal of Cancer* 106, no. 3 (January 31, 2012): 596–602.
25. Blount, A M. “Amphibole Content of Cosmetic and Pharmaceutical Tales.” *Environmental Health Perspectives* 94 (August 1991): 225–30.
26. Bluemel, G., F. Piza, and Zischka-Konorsa W. “[Experimental animal research on the tissue reaction to starch and talc powder after their intraperitoneal use].” *Wiener klinische Wochenschrift* 74 (January 1962): 12–13.
27. Blumenkrantz, M. J., N. Gallagher, R. A. Bashore, and H. Tenckhoff. “Retrograde Menstruation in Women Undergoing Chronic Peritoneal Dialysis.” *Obstetrics and Gynecology* 57, no. 5 (May 1981): 667–70.
28. Boorman, G. A., and J. C. Seely. “The Lack of an Ovarian Effect of Lifetime Talc Exposure in F344/N Rats and B6C3F1 Mice.” *Regulatory Toxicology and Pharmacology: RTP* 21, no. 2 (April 1995): 242–43. <https://doi.org/10.1006/rtpb.1995.1035>.
29. Booth, M., V. Beral, and P. Smith. “Risk Factors for Ovarian Cancer: A Case-Control Study.” *British Journal of Cancer* 60, no. 4 (October 1989): 592–98.
30. Bottazzi, Barbara, Elio Riboli, and Alberto Mantovani. “Aging, Inflammation and Cancer.” *Seminars in Immunology*, November 5, 2018. <https://doi.org/10.1016/j.smim.2018.10.011>.
31. Bulbulyan, M. A., S. A. Ilychova, S. H. Zahm, S. V. Astashevsky, and D. G. Zaridze. “Cancer Mortality among Women in the Russian Printing Industry.” *American Journal of Industrial Medicine* 36, no. 1 (July 1999): 166–71.
32. Bunderson-Schelvan, Melisa, Jean C. Pfau, Robert Crouch, and Andrij Holian. “Nonpulmonary Outcomes of Asbestos Exposure.” *Journal of Toxicology and Environmental Health. Part B, Critical Reviews* 14, no. 1–4 (2011): 122–52. <https://doi.org/10.1080/10937404.2011.556048>.

33. Buz'Zard, Amber R., and Benjamin H. S. Lau. "Pycnogenol Reduces Talc-Induced Neoplastic Transformation in Human Ovarian Cell Cultures." *Phytotherapy Research: PTR* 21, no. 6 (June 2007): 579–86. <https://doi.org/10.1002/ptr.2117>.
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35. Camargo, M. Constanza, Leslie T. Stayner, Kurt Straif, Margarita Reina, Umaima Al-Alem, Paul A. Demers, and Philip J. Landrigan. "Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-Analysis." *Environmental Health Perspectives* 119, no. 9 (September 2011): 1211–17.
36. Capital Breast Care Center, Georgetown University. "Ovarian Cancer." Capital Breast Care Center, April 14, 2016. <https://capitalbreastcare.georgetown.edu/health/ovarian>.
37. Capital Breast Care Center, Georgetown University. "Ovarian Cancer." Capital Breast Care Center, July 3, 2018. <https://capitalbreastcare.georgetown.edu/health/ovarian>.
38. Carr, C.J. "Talc: Consumer Uses and Health Perspectives" 21 (1995): 211–15.
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49. JNJ000062359
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51. JNJ000063951
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98. JNJMX68_000003728
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100. JNJMX68_000013019
101. JNJMX68_000013945
102. JNJMX68_000017827
103. JNJNL61_000079334
104. LUZ013094/P-26
105. P-321
106. P-47
107. PCPC_MDL00062175
108. PCPC0075758
109. RJLEE-001497
110. WCD 002478 - Exhibit 32 Waldstreicher
111. Pltf_MISC_00000272 (JANSSEN-000001-19) 1962.
112. RA00461
113. RA00462
114. RA00469-70
115. RA00471-72
116. RA00473
117. RA00474
118. RA00475
119. RA00476
120. RA00477-78
121. JNJTALC001465273

Exhibit C

Judith Wolf, MD
Medical Legal Testimony in last 4 years

Date: January 7, 2019

Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability
Litigation MDL No. 2738

Date: August 30, 2021, and August 31, 2021

Ellen Kleiner v. Johnson & Johnson, et al.
Court of Common Pleas, First Judicial District of Pennsylvania

Date: September 13, 2021, and September 14, 2021

Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability
Litigation MDL No. 2738

Date: January 10, 2024, and April 25, 2024

Johnson & Johnson Talcum Powder Products Marketing, Sales Practices and Product Liability
Litigation MDL No. 2738

Date: April 25, 2024

Brandi Carl and Joel Carl v. Johnson & Johnson, et al.
United States District Court for the District of New Jersey

Hourly Rate: \$650/hour